NHS Scotland Assure
Quality in the healthcare environment

NHS National Services Scotland

NHS Greater Glasgow and Clyde Radionuclide Facility Key Stage Assurance Review

OBC KSAR Report

Table of Contents

Document Overview

NHS Greater Glasgow & Clyde | Radionuclide Facility | Key Stage Assurance Review Report | OBC Stage

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Document Control Sheet

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Approvals

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1. Executive Summary

The existing Radionuclide Dispensary (RND) has operated from its current location for 30 years. It provides a daily service of manufacturing radiopharmaceutical medicines and distribution of them to Nuclear Medicine Departments throughout health boards in West Central Scotland and the West of Scotland, collectively providing services to 3/5th of the Scottish patient population. In order to facilitate this level of production, the RND has become the largest centralised Radiopharmacy in the UK manufacturing 35,000 individual patient doses annually. Due to the existing building's limitations for alterations and operating under a lease agreement, this project will develop proposals for the relocation of the service.

As a result of the Outline Business Case (OBC) Key Stage Assurance Review (KSAR) review and based on the information presented to NHS Scotland Assure, we are unable to support the project progressing to Full Business Case (FBC) at this time.

There are a number of key elements that NHS Greater Glasgow and Clyde (NHS GGC) should address as part of their action plan, prior to moving to the next phase of the project. NHS Scotland Assure (NHS SA) noted particular concern around the following items:

1. The current design does not demonstrate how NHS GGC will ensure compliance with NHS Scotland Net Zero policies as defined in "***A policy For NHS Scotland on the Climate Emergency and Sustainable Development - DL (2021) 38***".
2. Many elements of the project appear to have been developed approximately two years ago and there is limited evidence to indicate that NHS GGC and their appointed designers have reviewed the proposals to ensure they are still valid and reflect current needs, regulation and guidance. There is no evidence to demonstrate user group reviews associated with the mechanical, electrical and public health (MEPH) installations.
3. There has been poor project governance around the lack of recording of meetings and user consultations through the design stages to date. This is particularly relevant due to the dormant period of the project with potential changes in personnel and circumstances. This Further extends to the lack of Authorised Engineering (AE) appointments and estates support.
4. There is no evidence that a consistent Infection Prevention and Control (IPC) contribution from the health board throughout the design has been provided.
5. There is no documented fire strategy and lack of specialist fire engineering support at this stage.
6. A lack of adherence to NHS GGC's own governance requirements that are defined within the ***"Project Execution Plan version 7.0***".
7. Elements of the design are not compliant with SHTM guidance with no approved derogation and mitigations in place. There are a number of derogations noted that appear not to have been reviewed or approved by NHS GGC.
8. Gaps are evident in the consideration of the resilience as noted later in the report, however, the resilience of the systems is not robust and could result in a break in production. There is no evidence that this has been considered or that contingency measures might be required.

9. There are a number of key roles, including IPC, noted with the **"Project Execution Plan, rev 7",** that are yet to be filled, which if remaining unfilled, may impact the health board's ability to make informed decisions and review risks.
10. There are concerns about the spatial fit within plant rooms (particularly in relation to the AHU) and the lack of evidence on space for access, future flexibility and replacement.
11. SEPA was identified at the project kick off meeting as an interested party who would require to be consulted on the drainage from the facility. There is no evidence of discussion with SEPA on the drainage. It was suggested that an existing SEPA discharge consent / license for the site may cover the new facility, but this was not documented.

There are however several positive elements that the KSAR has identified, which include long commissioning periods already identified in the project programmes, the detailed user requirements and performance specification around the clean rooms.

1.1 Summary of Findings

The findings of this report have been collated based on information provided by NHS Greater Glasgow & Clyde. The following table outlines the status of key findings as derived from the KSAR and identified within the NHS SA Recommended Action Plan issued to NHS Greater Glasgow & Clyde under separate cover:

Review	No. of Issues per category				
	1	2	3	4	5
Project Governance and General Arrangements	1	7	5	3	0
Water and Internal Plumbing / Drainage Systems	0	4	7	6	1
Ventilation	0	7	10	14	5
Electrical	0	11	17	18	2
Medical Gases	N/A	N/A	N/A	N/A	N/A
Fire	0	0	6	6	0
Infection Prevention and Control Built Environment	0	1	1	5	0

The following categories were used in relation to the findings:

Category	Definition
1	Significant – Concerns requiring immediate attention, no adherence with guidance
2	Major – Absence of key controls, major deviations from guidance
3	Moderate – Not all control procedures working effectively, elements of noncompliance with guidance
4	Minor – Minor control procedures lacking or improvement identified based on emerging practice
5	Observation and improvement activity

1.2 Project Overview

Since April 2016, the former Western Infirmary Site has become part of the University of Glasgow Gilmourhill Campus. The grounds on which the current Radionuclide Dispensary Building is located are now under ownership and management of University of Glasgow, from which NHS GGC operate and maintain the current Radionuclide Dispensary Unit via a lease agreement with the University. The University have produced a Masterplan to re-develop the site, which involves the demolition of the former NHS GGC buildings, including the existing Radionuclide Dispensary. Therefore, NHS GGC have identified an urgent requirement to relocate the facility to a new location. NHS GGC has confirmed that the project is to progress on the basis of the preferred Shelley Court site on the Gartnavel Campus.

NHS GGC have appointed a Principal Supply Chain Partner (PSCP) to deliver the project where they are also responsible for the design. The scope of the project is to construct a cleanroom facility for manufacturing of radiopharmaceutical medicines and distribution of them to Nuclear Medicine departments throughout Health Boards in West Central Scotland and other medical customers.

Whilst not a patient facility, there are considerable critical radiopharmaceutical manufacturing operations that the Radionuclide department facilitates.

The selected site within the Shelley Road car park on the Gartnavel Campus presents unique challenges of its own, which must be considered. Not only in terms of the Radionuclide project, but also the safe ongoing operation of facilities, such as the Maggie's Centre, which sits adjacent to the proposed Radionuclide location.

The building form is set across two storeys with the upper storey being exclusively for supporting plant. The ground floor includes the pharmaceutical accommodation with supporting offices and changing areas. Uniquely the pharmaceutical accommodation is to be procured using a specialist subcontractor.

The primary services, such as electricity and water all originate from within the private networks of the Gartnavel General Hospital Campus and will be subject to connection requests and liaison with the existing site estates team.

The project includes significant electrical, domestic water, drainage and ventilation elements. There are no specific fire engineering proposals within the project design. These elements will be discussed in more detail throughout this Review.

The roof is also used to mount solar photovoltaic (PV) panels, which will provide renewable energy to the building.

2. Review Methodology

2.1 Overview of NHS Scotland Assure & The KSAR Process

Good management and effective control of projects is an essential element to the successful delivery and maintenance of healthcare facilities across NHS Scotland estates.

The NHS Scotland Assure - Assurance Service was launched on 1 June 2021 following a letter issued by Scottish Government to Health Board Chief Executives, Directors of Finance, Nursing Directors and Directors of Estates. The letter outlined the purpose of NHS SA, with an overarching aim to deliver a co-ordinated approach to the improvement of risk management in new builds and refurbishment projects across NHS Scotland. The new service will underpin a transformation in the approach to minimising risk in our healthcare buildings and environments, protecting patients from the risk of infection and supporting better outcomes for patients in Scotland.

From the 1 June 2021, all NHS Board projects that require review and approval from the NHS Capital Investment Group (CIG) will need to engage with NHS SA to undertake key stage assurance reviews (KSARs). Approval from CIG will only follow once the KSAR has been satisfactorily completed. The KSARs have been designed to provide assurance to the Scottish Government that guidance has been followed. The Scottish Government may also commission NHS SA to undertake reviews on other healthcare built environment projects. This does not change accountability for the projects; NHS health boards remain accountable for their delivery. NHS SA will be accountable for the services it provides that support delivery of the projects.

NHS Scotland Assure will also work closely with health boards to identify where a KSAR may be required for projects under their Delegated Authority, utilising a triage system to assess risk and complexity of projects.

The KSARs will assess if Health Boards Project Management teams (inclusive of clinicians, appointed construction consultants, and contractors) are briefed and following best practice procedures in the provision of facilities. We will review if projects are compliant in all aspects of safety, if specific engineering systems are designed, installed and commissioned, and for ongoing safety maintenance including Infection Prevention and Control (IPC).

The KSAR focuses on key topics, specifically – IPC, water, ventilation, electrical, plumbing, medical gases installations and fire. This ensures they are designed, installed and functioning from initial commissioning of a new facility and throughout its lifetime. Health Boards are required to have appropriate governance in place at all stages of the construction procurement journey.

The purpose of the KSAR at Outline Business Case (OBC) stage is to confirm there is a good and comprehensive understanding of the category of patient who will use the proposed facility and that the project team consider how appropriate quality and safety standards will influence the design. It looks to provide assurance that the project can proceed to the Full Business Case.

Whilst the KSAR focusses on actions to improve the end product, it is not intended to detract from the merits of a development that will add significant benefit for the healthcare of the population served, and which has many exemplary elements. Rather, it is a reflection of the complexity of healthcare construction projects and the stage of development at which it was reviewed. Some conflicts and changes are to be expected as complex projects develop and project teams have in place mechanisms to identify and address these. This report adds a layer of scrutiny and assurance to that process to address the above requirement from government.

2.2 KSAR Process

2.2.1 The OBC KSAR took place between 9 December 2021 and 1 June 2022.

2.2.2 To inform the findings of the KSAR, the health board were issued with key documents outlining the assurance question set and expected level of evidence and supporting documents in accordance with relevant legislation and guidance. This included the OBC KSAR Workbook and OBC Deliverables list.

The KSAR report includes an overview of the main findings of the review, with a further itemised list of detailed observations included within the appendices of the report. The detailed observations are recorded in an action plan that should be adopted by the Health Board following the review and subsequently monitored by them to ensure appropriate actions are completed in a timeous manner.

2.3 Application of Standards & Legislation

2.3.1 Health Facilities Scotland (HFS) currently provides a range of advisory and delivery services across a wide variety of topics from a portfolio which covers the built estate, engineering and environment and facilities management. With some exceptions these services are largely advisory in nature, identifying best practice and developing national guidance and standards.

2.3.2 Antimicrobial Resistance and Healthcare Associated Infection (ARHAI) Scotland currently provides advice and guidance on all aspects of infection protection and control nationally in Scotland, inclusive of expert advice and guidance on the topic of Healthcare Associated Infections (HAI) and antimicrobial resistance. It maintains and continues to develop a practice guide (National Infection Prevention and Control Manual – NIPCM) as well as a HAI Compendium of all extant guidance and policy appropriate for use in NHS Scotland. Like HFS, these services are largely advisory in nature, identifying best practice and developing national guidance and standards. The NHS Scotland NIPCM was first published on 13 January 2012 as mandatory guidance, by the Chief Nursing Officer (CNO (2012)1), and updated by a second edition on 17 May 2012 (CNO(2012)01-update). The NIPCM provides guidance for all those involved in care provision and should be adopted for infection, prevention and control practices and procedures. The NIPCM is mandatory policy for NHS Scotland.

The authority of guidance produced by National Services Scotland (NSS) and other national organisations e.g. Healthcare Improvement Scotland is best described by the definitions outlined below (SHTM 00 – Best practice guidelines for healthcare engineering):

> **Regulations** are law, approved by Parliament. These are usually made under the Health and Safety at Work etc Act following proposals from the Health & Safety Commission. Regulations identify certain risks and set out specific actions which must be taken.
>
> **Approved Codes of Practice** give advice on how to comply with the law by offering practical examples of best practice. If employers follow the advice, they will be doing enough to comply with the law.
>
> Approved Codes of Practice have a special legal status. If employers are prosecuted for a breach of health and safety law, and it is proved that they did not follow the relevant provisions of an Approved Code of Practice, they will need to show that they have complied with the law in some other way, or a court will find them at fault.
>
> **Standards (**British or European), institutional guides and industry best practice play a large part in how things should be done. They have no direct legal status (unless specified by Regulations). However, should there be an accident; the applied safety practices at the place of work would be examined against existing British or European Standards. It would be difficult to argue in favour of an organisation where safety was not to the described level.
>
> **Guidance** is issued in some cases to indicate the best way to comply with Regulations, but the guidance has no legal enforcement status.

2.3.3 Whilst guidance is deemed not compulsory by the Health and Safety Executive (HSE), where compliance with guidance is specified in a contract, as is the case here, it becomes a contractual requirement. Therefore, any permitted deviation from it would be expected to follow a formal process with input from all relevant parties, with clarity around how the outcome was reached, including risk assessments where appropriate and sign off by all those authorised to approve it.

2.4 Project Technical Outline Summary

The following section outlines the current NHS GGC proposals in relation to the new Radionuclide facility. It is not intended to be a technical appraisal of the systems nor an endorsement of solutions by NHS SA. Where we have identified non-compliances, derogations or variances from guidance or standards, these are discussed elsewhere within the KSAR report.

This new build facility is divided into two key areas. The “hot” side includes for the laboratory manufacturing facility and the “cold” side includes for the supporting ancillary staff and office accommodation. The upper floor plantroom above the “hot” side is known as the “dry” plantroom and above the “cold” side is known as the “wet” plantroom.

The new build facility is proposed to be largely supplied directly with cold water from the raw external Mains Cold Water Supply (MCWS). There is no bulk storage and no filtration proposed for the incoming cold-water systems within the building. The lack of filtration and lack of storage are derogations, which have not been recorded as approved by NHS GGC.

Within the “cold” side of the building this direct MCWS will serve the cold-water outlets and the local electrical Point of Use (PoU) water heaters which will in turn provide a Domestic Hot Water Supply (DHWS).

The ventilation strategy for the facility is also divided into the “hot” side and “cold” side. There are two distinct systems for each space. The “hot” side system is a cascade ventilation system used to control the cleanliness of the various laboratory spaces and provide the required level of heating and cooling to control the internal temperature of the spaces. The laboratory system is identified as being designed in accordance with EU GMP Volume 4, Annex 1. “EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use”.

The ”cold” side system is a typical, non-clinical, supply and extract system with separate dirty extract for the WC spaces. The perimeter ground floor office and training rooms are proposed to use natural ventilation from openable windows.

The laboratory spaces also include for fume cupboards with Local Exhaust Ventilation (LEV) systems.

The facility is to be supplied from a new 500kVA LV transformer connected into the existing HV infrastructure within the Gartnavel General Hospital site. A backup power supply is proposed via a 500kVA generator.

Lighting and emergency lighting is detailed within the OBC design information. Within the laboratory areas there will be a minimum of two lighting circuits per space to ensure that if one circuit is lost there will be the provision of 50% redundancy in the room.

The information details a photovoltaic array on the roof with the current roof area permitting space for a photovoltaic array of approximately 269m2 generating a potential 42kW of renewable energy.

Fire alarm systems are provided via automatic detection and VESDA systems. The VESDA system is provided to the hot side and automatic detection provided to the cold side. The drawings and documentation note L1 protection as per BS5839.

3. KSAR Review Summary

The following narrative relates directly to the OBC KSAR workbook and the evidence indicated therein. The comments associated with the points are because of the evidence presented by the Board and their advisors during the review process.

3.1 Project Governance and General Arrangements

3.1.1 Project Governance and General Arrangements KSAR Observations

Workbook Ref No.	Areas to probe	Evidence expected
1.1	Evaluation of changes detailed from previous KSAR.	Assessment of any substantive changes in highlighted areas from previous review stage and all actions have been implemented.
NHS Scotland Assure Observations: This question is not relevant to this KSAR as the project entered the KSAR process at the OBC (this) stage.		

Workbook Ref No.	Areas to probe	Evidence expected
1.2	Verification that CIG recommendations have been implemented with respect to prescribed in scope areas.	Review of the implementation of all CIG recommendations. Evaluation of any deviation from previous submissions or reviews.
NHS Scotland Assure Observations: NHS GGC have not evidenced any historic CIG recommendations within their KSAR response.		

Workbook Ref No.	Areas to probe	Evidence expected
1.3	Has cross-referencing with NDAP and AEDET recommendations been implemented?	An assessment if there is full compliance with the applicable recommendations and actions from the preceding step.

NHS Scotland Assure Observations:

The project originally underwent an OBC NDAP prior to the launch of NHS SA. The project then paused and re-started at OBC stage. There is no evidence to support significant progression of the original points raised, with the KSAR identifying a number of points that were still to be addressed by NHS GGC. NHS GGC have noted verbally that they plan to address these at FBC. NHS SA have noted the key priorities that, in their opinion, should be addressed by NHS GGC prior to commencing FBC stage, within the executive summary and throughout the KSAR.

Workbook Ref No.	Areas to probe	Evidence expected
1.4	Does the Health Board continue to demonstrate service / clinical input into design decisions based on a current and comprehensive knowledge of patient cohorts?	Recorded and updated input taken from service lead(s) / clinician(s) about relevant patient cohort characteristics and their typical needs in terms of the accommodation's environment, safety and infection control standards. Demonstrable expertise of service lead(s) / clinician(s) in providing this advice.

NHS Scotland Assure Observations:

There is limited evidence provided to confirm that there has been ongoing user engagement with the key stakeholders. There is also a lack of evidence to record the expertise of the key stakeholders in providing project related advice and direction.

The primary client project briefing document is the ***'User Requirement Specification, rev P06'***, prepared by a number of key users, including the Directors of Diagnostics and Pharmaceutical Services, General Manager for Diagnostics, the Head of Radiopharmacy and the Regional QA Pharmacist. The specification is concise and provides a solid base of requirements that the design team can prepare strategic and design information. The change control at section 14.0 of the document notes that versions, B, P05 and P06 were updated following reviews with stakeholders, indicating that there has been continued user input to the briefing information.

Whilst the change control section has been completed as noted above, there is no recorded evidence of ongoing user engagement, beyond the user requirements specification and there are no records of user risk assessments with regards to specific servicing provisions or guidance elements as the design has progressed.

NHS GGC advised verbally during the KSAR workshops, that the users were also involved in the creation of the environmental matrix and ADB sheets, however this is not confirmed with minutes or meeting records.

There is reference to input from user groups at the initial setting out stage within the stage 1 and stage 2 design report, with the process of engagement defined and the resultant outputs included by the Architect in developing the layouts. Three technical design notes have been issued in relation to the resilience, utilities and water management strategies, however, these do not make reference to engagement with Estates or document the reliance on existing site infrastructure. In addition, there are no user group reviews associated with the mechanical, electrical and public health (MEPH) installations. There has been information provided subsequently in emails to suggest meetings have taken place.

No evidence has been provided of ongoing client stakeholder review including input/sign off from user groups and infection control team to document an input from ICD or microbiologist as required by ***SHFN 30: Part A (1.2 – 1.8).***

Workbook Ref No.	Areas to probe	Evidence expected
1.5	Project team continues to demonstrate a unified and recorded understanding of needs of main users and patient cohorts of the proposed accommodation and how this has influenced the design of critical building, engineering and infection prevention and control quality and safety standards.	Updated and current list available of all stakeholders, service users and patient cohorts impacted by this project, plus the identification of any high risk groups and their specialist needs. Updated and recorded engagement on these designs issues having taken place between the project team and service lead(s) / clinician(s), infection prevention and control team, and other key stakeholders (e.g. Estates, Medical Physics, IPC, the AEDET, NDAP or other design briefing workshops). Details available of how service users / patient cohort needs and their expected use of the accommodation are influencing the design brief; including critical building, engineering and infection prevention and control quality and safety standards.

NHS Scotland Assure Observations:

Whilst the facility does not provide direct care to patients, it is an extremely important facility used to manufacture radiopharmaceutical products.

The development of clean rooms to “Good Manufacturing Practice” standards indicates a response to those needs in the design. However, the resilience of the MEP systems is not robust (for example no segregation/diverse routes of key infrastructure and little in the way of documented evidence to support risk assessments of operation of key plant such as ventilation) and could result in a break in production.

For example, the technical note "*TDN01-MEP Resilience"* presented, specifically discuss the electrical supply to the project within the site and does not reference to the wider site infrastructure that is served from that high voltage circuit of the site wide electrical infrastructure.

A list is available of the various key stakeholders for the project, however not all roles are currently filled with an identified person. Infection Prevention and Control, Authorising Engineers, Estates and Facilities Management are notably missing. There is little evidence provided in the form of stakeholder engagement during the design process. From the KSAR workshops, NHS GGC have indicated that these roles are to be filled as the project progresses however there is no documented gap analysis or strategy to support this.

Within the ***"Project Execution Plan, rev 7"***, under section 3.2, the named Project Board members are identified along with their roles. There are a number of notable exclusions including Estates, FM, Infection Control and Planning Manager who are noted as TBC. With reference specifically to Estates and FM, there are site specific considerations with regard to the Gartnavel campus that will have an impact on the design strategies and works execution, which will require the input of these representatives.

Whilst this project does not specifically provide direct care to patients, there are a number of infection control elements to be considered, which will impact other aspects of the site, such as a dust and noise impact on adjacent buildings like Maggie's Cancer Centre. The Stage 1 HAI-SCRIBE documentation makes little reference to the works beyond dust spread across the site and has not fully considered the impact on other clinical facilities within the vicinity of the site.

User service requirements and Project Execution Plan (PEP) documentation are aligned in terms of the project Board nominated individuals with the exception of a named IPC representative who appears to have been part of the approval team on the user requirements document and not named in the PEP. There is no IPC representation noted in the stage 1 HAI-SCRIBE document. The inclusion of nominated infection control representatives would have a positive impact on the design strategies and works execution.

Workbook Ref No.	Areas to probe	Evidence expected
1.6	Planned approach towards determining the necessary standards for this accommodation.	Updated and current list of the relevant NHS and non-NHS guidance that is being used and adopted (see previous section of workbook OBC KSAR (Page 9) for examples of appropriate guidance). Updated and current list of all proposed derogations from NHS guidance with a detailed technical narrative on each derogation and/or list of known gaps in guidance that will need to be resolved in order to meet the needs of the patient / user cohort. Knowledge of the role of infection prevention and control and microbiologist advisors to be used throughout the design stages, and

		details of the resource plan in place to ensure this advice will be available.

NHS Scotland Assure Observations:

There is evidence of prescribed design guidance that the Board require to be used. There is a derogation schedule available, however it does not reflect the non-compliance of certain elements of the design that have been identified during the KSAR. There is no evidence that the IPC team has been engaged in ongoing design reviews or contributions to the design.

The primary client project briefing document is the ***'User Requirement Specification, rev P06'***, prepared by a number of key users including the Directors of Diagnostics and Pharmaceutical Services, General Manager for Diagnostics, the Head of Radiopharmacy and the Regional QA Pharmacist. The specification is concise and provides a solid base of requirements that the design team can utilise to prepare strategic and design information. The project execution plan (PEP), rev P07 prepared by the Project Manager notes the healthcare guidance and a hierarchy of design. There is a mixture of GMP and SHTM guidance to be considered. This is noted also in the ***'User Requirement Specification, rev P06'***. The document does not make reference to SHTM81 and there appears to be significant confusion as to the applicable fire guidance documents. Whilst inferred in the user requirements specification, there is no specific reference to user engagement or technical workshops to determine the required standards, for all affected engineering services.

There are two separate derogation schedules provided for review. ***'RND-CDL-XX-XX-SC-MEP-Derogations Schedule'*** and ***'RND-GRA-XX-XX-SC-W-28560_Rev1'***.

It was confirmed during the KSAR Weekly Review Meeting on the 19th January 2022 that ***'RND-GRA-XX-XX-SC-W-28560_Rev1'*** is the correct version.

There is no evidence to suggest that the derogation list has been reviewed by the relevant stakeholders. '***RND-GRA-XX-XX-SC-W-28560_Rev1***' notes a number of derogations that do not include NHS GGC comments or an agreed acceptance date. It is therefore unclear as to whether these are endorsed or accepted by NHS GGC.

The Responsibility Assignment Matrix (RAM) indicates an IPC lead nurse as resource for the project and has identified specific points in the project when their input would be required. There is no reference to the ICD or microbiology resource.

Workbook Ref No.	Areas to probe	Evidence expected
1.7	How does the Health Board demonstrate that there is an effective infection prevention and control management structure in place and how does it relate to the development of the project?	Evidence IPC and clinical teams have been integrated into all decisions regarding any derogations through the design process and are satisfied this will not impact on patient safety such as, specific sign off, supporting meeting minutes, risk assessments, risk registers relating to IPC with evidence of escalation through the agreed NHS Board governance process.

	How does the Health Board demonstrate leadership and commitment to infection prevention and control to ensure a culture of continuous quality improvement throughout the organisation and that there is an effective IPC structure in place and how does it relate to the design development?	

NHS Scotland Assure Observations:

There is limited evidence of a **documented** integrated IPC strategy for the project. There is no evidence that the IPC team have been engaged to review derogations or escalated any to the Board throughout the design stage. It is also unclear as to whether the IPC team were involved in the Stage 1 HAI-SCRIBE production.

The HAI-SCRIBE has been developed however it does not fully consider the impact of the works on other clinical spaces within the site. There is no evidence of supporting information such as risk assessments or minutes in support of the Stage 1 HAI-SCRIBE production.

The HAI-SCRIBE Stage 1 presented is no longer in keeping with the technical documentation provided by the Board for this OBC KSAR as it has advanced to a position where a Stage 2 HAI-SCRIBE could be prepared.

There is no evidence provided of the IPC Management Structure or IPC Management Team, documenting the necessary expertise and leadership skills to support the design work nor of the process of escalation.

Workbook Ref No.	Areas to probe	Evidence expected
1.8	Integration with Authority Policies and Operation How does the Board demonstrate implementation of evidence based infection prevention and control measures?	The Health Board can demonstrate the current version of the National Infection Prevention and Control Manual has been adopted by the organisation and all staff are aware of how and where to access this. (Ask staff). IPC are fully embedded in the project team and the OBC programme-taking cognisance of any actual or perceived risks identified provided.

NHS Scotland Assure Observations:

The HAI-SCRIBE Stage 1 identifies a number of hazards, risk and mitigation measures.

However, there is no description as to how the National Infection Prevention and Control Manual (NIPCM) will be applied in the project, nor if the IPC team were engaged in the process.

As there is no nominated IPC representative within the Project Board, it is unclear as to how their interests will be represented at a strategic level within the project governance structure. It is noted that in the Responsibility Assignment Matrix (RAM) includes a named Lead Infection, Prevention and Control Nurse. The RAM confirms that IPC should have been consulted at the following stages:

- IA – Establishing PM & Technical Documentation.
- IA – Establishing Design Information.
- OBC – Economic Appraisal.
- OBC – KSAR
- OBC – PM and Technical Documentation.
- OBC – Design Information.
- FBC – PM and Technical Documentation.
- FBC – Design Information.

And informed on:

- FBC – CDM Information.
- Construction – Project Monitoring.

There is no evidence to demonstrate that IPC have been engaged as outlined in the RAM.

Workbook Ref No.	Areas to probe	Evidence expected
1.9	The Health Boards Infection Prevention and Control Strategy	Assessment of the Health Boards approach to all IPC related matters in relation to the development of the design, HAI-SCRIBE etc. IPCT annual programme of work.

NHS Scotland Assure Observations:

There is limited evidence of a documented IPC strategy associated with the Radionuclide Dispensary Project, nor is there any evidence to suggest that IPC have been involved in the delivery of any of the IA or OBC actions from the RAM.

The RAM itself is not a strategy document, however a programme of touchpoints where IPC should be involved. There is no documentary evidence available to confirm any of these have occurred.

Stage 1 of the HAI-SCRIBE has been completed, but IPC involvement has not been recorded at the various stages of the project that are identified in the RAM.

Workbook Ref No.	Areas to probe	Evidence expected
1.10	The Health Boards Monitoring and Records	Evidence that the Health Board integrating this project with wider IPC requirements within the context of the OBC. For example, evidence that the proposals for equipping incorporate IPC requirements?

NHS Scotland Assure Observations:

There is little reference to IPC within the user requirements specification and the PEP, which are the Health Boards defined governing requirements for the technical and governance aspect of the Radionuclide Dispensary project. As noted previously IPC involvement has not been recorded at the various stages of the project that are identified in the RAM

The Stage 1 HAI-SCRIBE makes reference to external works and their impact on other buildings within the site. Specifically, ground conditions, dust and future expansion. The document was prepared NHS GGC, however any attendees present at the appraisal are not recorded, beyond the author.

Only a Stage 1 HAI-SCRIBE has been completed, however to incorporate equipping requirements and other elements of IPC risks, a Stage 2 HAI-SCRIBE would be required (or at least commenced).

The RACI Matrix noted that the equipper has not as yet been resourced, and the associated grouping of equipment and furniture has not been identified.

Workbook Ref No.	Areas to probe	Evidence expected
1.11	Planned approach for managing the design process to ensure successful compliance with agreed and approved standards.	The project governance arrangements and resource plan in place to ensure that the necessary decision-making authority and technical expertise is available to take responsibility for and deliver the project as planned and agreed. Details of how gaps in expertise are being filled. Details of how compliance with the appropriate guidance, design brief and other standards are being agreed, signed off, monitored, reported against and if necessary escalated / adjudicated throughout the design, construction and commissioning stages. Details of how all stakeholders' interests are being agreed, signed off, monitored, reported against and if necessary escalated/

		adjudicated throughout the design, construction and commissioning stages.

NHS Scotland Assure Observations:

The Board have prepared a ***'User Requirement Specification, rev P06'***, which notes the various contributing stakeholders and their associated titles. IPC are not represented on this document. The ***'18CP002-RND Responsibility Assignment Matrix, v0.1'*** notes a number of Board stakeholders and project team members with identified responsibilities.

There is no evidence of roles and responsibilities associated with the acceptance and review of design information for the stakeholders (including technical stakeholders). Whilst the PEP puts the onus on the health board for final design sign off, it is unclear as to how the health board will utilise advice of other stakeholders to make informed decisions. NHS SA note this places a significant responsibility on the Health Board in the absence of any other defined contribution from technical and subject matter expert stakeholders.

There is no recorded evidence of stakeholder's interests being accepted or reviewed. Nor is there any record of how and when that will happen.

Within the PEP, under section 10, the health board have presented a methodology for design, quality management and commissioning. Within this section, the applicable healthcare guidance and statutory regulations are stated, the approach to BREEAM and Net Zero Carbon and HAI-SCRIBE are defined.

Section 10.2 notes *"The design proposals will require to be accepted progressively by the Stakeholders, concluding with client authorisation."* There is no evidence of design engagement or acceptance with stakeholders.

Section 10.2 of the PEP discusses design development and acceptance, which confirms the procedural aspects of drawing approval, where the Board have full responsibility for the approval system of all design documentation. This includes all technical design drawings, briefing notes and specifications. The Board has a responsibility to assign either of the following status to each item;

- Status A – Approved
- Status B – Approved with minor comments resulting in an update
- Status C – Not approved

The PEP does not acknowledge the required technical expertise to ensure these obligations can be achieved. There is no evidence as to whether this expertise or resource exists currently within the project (on the approval side) or whether the Board can call on such expertise elsewhere within their organisation. It is also recognised that the Board have not appointed Authorising Engineers for each of the core AE subjects;

- Ventilation
- Water
- Electrical

The change control process is defined in section 10.6 of the PEP and identifies that any deviations from the user requirement specification are to be submitted to the Project Board for approval, outlining cost, quality and programme impact. A decision log has been created to record such deviations and notes an approver and references to the minutes or decision making process.

It is noted that the Project Board has no technical nor IPC representatives identified as part of the technical documentation provided by the Board.

The derogation schedule provides no evidence that IPC team has been involved in project derogation discussions/sign off or that derogations have been escalated through the project governance or IPC escalation processes.

The PEP details how the project will be managed and governed and that each responsible person can escalate issues however, does not document the detail of escalation processes to be followed. This is inclusive of the IPC team and escalation to the HAI executive lead.

Workbook Ref No.	Areas to probe	Evidence expected
1.12	The Health Boards approach on the procurement journey with evidence of the plans on how the Board will provide assurance, particularly emphasis on the critical system identified earlier.	Evidence on how Infection Prevention and Control are involved with the conceptual procurement approach to the design stage and future plans for project. Plans to identify any gaps in the procurement approach that may require to be addressed. Evidence on how the Infection Control procedures and management will fit with the conceptual procurement approach and initial thinking on how it will be managed. Evidence of a detailed procurement strategy report. Evidence that the Health Boards selected procurement route has gone through the Health Board's Governance channels.

NHS Scotland Assure Observations:

There is no evidence of role IPC will play in the overall procurement strategy and there is no evidence of a detailed procurement strategy report that would ultimately demonstrate the Health Board's approach to a co-ordinated delivery of all elements of the project including but not limited to the PSCP appointment, cleanroom specialist requirements and equipping.

It is recognised that evidence is provided with regard to the procurement of the Contract Administrator, Project Manager and PSCP. There is no wider procurement documentation that demonstrates an integrated approved approach to the overall project requirements.

There is no evidence of the integration of IPC within the project's technical decision-making process.

Appreciating that this project has no direct patient facing elements, there are a number of elements where IPC has a considerable impact within and out with the facility itself as noted within the Stage 1 HAI-SCRIBE documentation.

Whilst there is no detailed procurement strategy provided for the whole project. The health board have provided a document entitled ***'Guidance for Planning, Design and Construction of new and upgraded Aseptic Facilities, issue number 1.2***'. This outlines a comprehensive approach to the planning, design and construction of such facilities and whilst not a detailed procurement report, offers a good level of information to determine the required tasks within the procurement stages.

Section 2.7 of the PEP includes narrative on the delivery of the project, which discusses the use of the NEC3 and 4 Professional Services Contract for the consultants and the NEC3 Principal Supply Chain Partner contract. **"***The various professional consultants (PSC) have all been appointed via the appropriate NSS (NHS) Framework Scotland 2 route which is detailed within the OBC."* The procurement of the PSCP services has been via a high-level information pack (HLIP).

There is no specific confirmation that the procurement route has gone through the Board's governance channels. However, by virtue of the presented HLIP and appointment of the PSCP by this route, it is expected that the procurement process would have a form of governance for the proposed team and implemented by all stakeholders. This is not recorded within the documentation.

There is no reference to microbiologist or ICD support to the project.

The facility has no inpatients but will manufacture radionucleotide treatments for vulnerable patient groups across the West of Scotland. The manufacture of those products are subject to MHRA regulations, however, IPC considerations will be required for staff and visitors working in, visiting the facility and also surrounding facilities during the construction period. NHS GGC have not confirmed if there will be an expectation for the facility to be audited by the IPC team.

Workbook Ref No.	Areas to probe	Evidence expected
1.13	The Health Boards approach on those areas of design that the procurement route has provided identification as possibly being Contractors Designed Portions (CDP's).	Evidence that the Health Board integrating this project with wider IPC requirements within the context of the OBC. For example, evidence that the proposals for equipping incorporate IPC requirements? Evidence that the procurement of the lead designer will encompass these areas in their oversight and sign off on the complete design. Evidence that a clear demarcation of design responsibility is being developed.

NHS Scotland Assure Observations:

The health board has not clearly identified what areas of the procurement route will be Contractor Design Portions.

The MEP Designer has prepared Document *"**RND-CDL-XX-XX-SC-ME-00001 Rev P01**"* which outlines the anticipated contractor design potions (CDPs), however these do not include the clean room designs and in particular the clean room ventilation. The HLIP associated with the procurement of the PSCP highlights the use of a specialist clean room contractor and the PSCPs are scored on the "proposed approach to engaging, appointing and managing specialist clean room contractor". It is therefore unclear how this appointment is being managed from a design development perspective or how it may impact on other consideration such as collateral warranties and design indemnities.

There is no evidence that the IPC requirements have been included in the design nor how they would be managed through the various design stages.

The equipping responsibility matrix includes information around the equipping lists, but no clear definition of what expectations are around the equipping procurement process.

The PEP does not make reference to Contractor Design Proposals and the management thereof. There is no process for ensuring that the general requirements of contractor design proposals are achieved and the responsible parties for doing the same.

Document *"**RND-CDL-XX-XX-SC-ME-00001 Rev P01**"* is provided which confirms the contractor design portions as provided by the MEP Design Engineer on behalf of the PSCP. This outlines some 15 items which will be subject to specialist designer input and not that of existing team members. The document outlines the expectations of that design and also the required documentation from the contractor to satisfy that expectation. There is no evidence provided to understand who is responsible for the procurement, acceptance and setting to work of these identified contractor design portions. The MEP Design Engineer, whilst having created the document, are not acting as lead designer.

The ***"Responsibility Assignment Matrix (RAM), v0.1"*** which outlines the roles, with named individuals (where available) and responsibilities at the key stages of the project business cases. This is clear with regards to each business case stage, however, does not refer to contractor design packages.

The equipping lead has not been allocated/resourced therefore evidence is not available at this stage for IPC input to equipping requirements.

Workbook Ref No.	Areas to probe	Evidence expected
1.14	Evaluation of the Health Boards commissioning plan.	Evidence that the Health Board has recorded plans that are comprehensive and adequate to address the needs of the project and that they are fully resourced.

NHS Scotland Assure Observations:

The **'*User requirements specification, version P06 - Section 8.0 Validation*'**, details a handover process that the PSCP must adhere to and collate in a written Qualification

Report. The document outlines the involvement of the Radiopharmacy and QA departments during testing and commissioning. Importantly, the user requirements specification goes on to discuss validation documentation in advance of construction, when more detailed design is available.

The PEP document is aligned with the user requirements specification in that it references the document and its obligations. The PEP goes on to identify the project commissioning group, which includes NHS GGC project management, IPC, project managers, MEPH commissioning managers, MEP designers and NHS GGC estates leads.

At this stage in the project, the developed programme notes a 12-13 week period of specialist commissioning. This is a single line in the programme and will require to be broken down at the next stage within the project.

There is no note of IPC or microbiologist input to the commissioning phase of the project.

Workbook Ref No.	Areas to probe	Evidence expected
1.15	Evaluation of the Health Boards duty holder matrix.	Evidence that the Health Board have a fully recorded matrix of the required roles and responsibilities and have a clear governance structure that is fully resourced together with plans in place for the implementation. Evidence that Health Boards have appropriate number of competent, qualified staff to carry out specific duties throughout the life cycle of the project e.g., IPC, Engineers, Estates staff etc. The number of competent, qualified staff will depend on the type and size of the Build Project.

NHS Scotland Assure Observations:

There is a comprehensive Responsibility Assignment Matrix (RAM), which outlines the roles and responsibilities of each named individual. These are broken down into disciplines and aligned with the requirements of each project stage across IA, OBC, etc.

The matrix does not make reference to any competency assessments on individuals or organisations engaged on the project. The provided evidence includes details of the HFS Framework 2 supply chain and the approved framework criteria where the supply chain and consultants are “deemed to be competent to design and deliver the project requirements.”

There is no evidence to suggest that a competency evaluation has been undertaken on the various parties to the design and reliance is sought on the framework approval process from the PSCP.

The health board competency check statements only refer to contracted teams, which include the contract administrator, project manager and PSCP. There is no evidence of the competency of the health Board project team (inclusive of pharmacists and IPCT). There is no plan shown to be applied should resource not be available or their experience is limited.

3.1.2 Project Governance and General Arrangements: Further Observations

In addition to the points raised via the KSAR workbook above, we also include the following observations as a result of the review, all of which relate to the evidence presented during the appraisal.

3.1.2.1	There is insufficient detail provided to provide comfort that the specific nature of the user requirements for testing and commissioning have been allowed for.
3.1.2.2	The required project sustainability targets i.e., Operational Energy Use targets or BREEAM Targets to be met by the project have not been identified. The PEP notes that "*As a new-build project, an NHS Scotland BREEAM "excellent" rating is required to be achieved. NHS GGC discussed this requirement with HFS through the OBC NDAP process and a pragmatic approach to BREEAM was agreed. A full BREEAM review was undertaken with a credits either unable to be achieved or adding no value to the project omitted. A resultant score of 28.5% "unclassified" was achieved."* The assessment carried out in ***'1023694_RPT-SY-004 - Zero Carbon Operation Review_RevC'*** indicates that the currently proposed design will not meet the current NHS Scotland Net Zero targets. It is therefore unclear as to how NHS GGC will meet the current NHS Scotland Net Zero policies as defined in "***A policy For NHS Scotland on the Climate Emergency and Sustainable Development - DL (2021) 38***".

3.2 Water and Internal Plumbing / Drainage Systems

3.2.1 Water and Internal Plumbing / Drainage Systems: KSAR Observations

Workbook Ref No.	Areas to probe	Evidence expected
2.1	Has the Health Board completed competency checks on the water and drainage consultant designers?	Recorded evidence that the design team are experienced and have a comprehensive knowledge of the relevant design standards. Where anyone does not have a record of extensive health care experience what recorded plans are to be put in place by the Consultant Designers? Recorded evidence that input from the Health Authorising Engineer for Water (AE(W)) has been requested.

NHS Scotland Assure Observations:

There is no primary evidence provided within the OBC submission that directly identifies the MEP Design Engineer's experience in water and drainage design. However, there is secondary evidence, which confirms that NHS GGC have reviewed and scored a Written Quality Submission, provided by the PSCP as part of the selection process. This required them to provide evidence of their proposed consultants and key individuals including Curriculum Vitae (CV) under the heading of "*Proposed Personnel".*

The Quality Submission also requested evidence of the PSCP's proposed MEP Designer's relevant similar experience, including case study examples. Whilst evidence of the process is provided, NHS SA were not provided copies of the actual CVs for review.

There is no recorded evidence to suggest that the Water and Internal Plumbing / Drainage Systems designs have been reviewed by an Authorising Engineer AE(W) appointed by NHS GGC. The Project Manager Project Execution Plan (PEP) *'**19945 GGC Radionuclide Dispensary - PEP Rev 7 28.10.21**'* identifies in Section 3.3 that "*A Project Steering Group will be formed from commencement of FBC Stage. The PSG's primary purpose will be to provide technical oversight to the project and provide a link to various stakeholders, such as the NHS GGC Authorising Engineers*".

Within Section 10.7 of the PEP it is noted that the **"***Authorising Engineer (Water) – to be confirmed as required"* by NHS GGC. There is no evidence of correspondence with or reviews from an AE(W). It is suggested in the PEP that an AE(W) will be required to be consulted at FBC stage.

Workbook Ref No.	Areas to probe	Evidence expected
2.2	How does the Health Board ensure that water services are designed in a fashion, which will retain space for minor additions and modifications to services in the future?	Evidence that the engineers are presented their co-ordination drawings (BIM model), with space for future flexibility identified, to the Board. Evidence that the Design Consultant has considered and agreed with the Board, space for future flexibility in the service installations. Evidence that the designers have presented each of the main service runs plus plant rooms to the Board's FM team, to highlight space for future flexibility. Evidence that the Board has agreed a strategy (percentage) for spare capacity and a documented allowance to be incorporated into the design. Are plant/tank rooms, IPS sections, horizontal distribution runs and risers appropriately sized for the equipment being installed and facilitate safe adequate maintenance.

NHS Scotland Assure Observations:

There is no evidence that the designers have presented their co-ordinated BIM model to the board. It is stated that a full BIM model will be available at FBC stage.

There are no ceiling void sections or detailed building sections provided showing the various building services systems in relation to the Structure and Architecture.

The design information includes only two simplified 3D views of the main upper floor plantroom on drawing ***'RND-CDL-XX-01-DL-M-50001'***. There is no evidence to suggest that a fully coordinated BIM model, or alternative techniques have been developed at OBC stage to demonstrate the key areas of coordination / "pinch-points" and future flexibility.

There is no evidence to suggest that the need for future flexibility within the water services and above ground drainage systems has been included as part of the project by the PSCP. The following statement is made within ***'GC&C RND OBC KSAR-Future Proofing Strategy Statement'*** on the need for Future Proofing. *"GGC confirm that over the previous five years, service demand has remained stable and consistent. Radiopharmaceutical manufacturer is determined by requests from nuclear medicine departments which in turn are regulated by the number of gamma cameras available. It is estimated that in RND's 40 plus year history patient demand and camera numbers have remained steady. It is not anticipated significant deviation from this position."* NHS GGC, as part of their KSAR response, quote this statement as the reason for not considering future flexibility in the design – it is however unclear as to how they have fully considered this from an MEP services perspective.

While the design drawings demonstrate the design intent and are generally to a RIBA Stage 2 level of detail as required at the OBC stage, there are some key omissions. They do not actively indicate any reserved future plant space or distribution space provision. The possibility of a requirement to increase water services or drainage system capacity in the future has not been identified within '***TDN 02 - Utilities Technical Note***' which is held within folder 8.4.

The Access and maintenance strategy within folder 22, drawing '***RND-OBE-XX-XX-DR-28002_A&M***', makes no specific reference to the water services system plant access, maintenance or future replacement. The packaged water tank is not shown on this drawing. There is no evidence to suggest spare capacity has been considered within the OBC stage design.

There are no ceiling void sections or detailed building sections provided showing the various building services systems in relation to co-ordination with the Structure and Architecture.

The water services systems presented on the design drawings include for a small, centralised packaged cold-water tank and booster set, with point of use electrical water heaters serving the sanitaryware. Access to the main plant for inspection and maintenance is not specifically identified on drawings '***RND-OBE-XX-XX-DR-28002_A&M', 'RND-CDL-XX-01-DL-M-50001***' or '***RND-CDL-XX-01-DL-M-50002***'.

Workbook Ref No.	Areas to probe	Evidence expected
2.3	How does the Health Board assure itself that all variations / derogations, which may be required to water systems, are investigated and agreed by all parties before they are incorporated in the design?	Evidence that each variation / derogation has a detailed technical analysis, has been referred to the Board, and agreed with their water management group clinical, engineering, Estates, infection prevention, control, and FM teams.

NHS Scotland Assure Observations:

There is no evidence of derogation reviews with the board and their stakeholders. Two separate derogations schedules were presented by NHS GGC as part of their KSAR response. '***RND-CDL-XX-XX-SC-MEP-Derogations Schedule***' and '***RND-GRA-XX-XX-SC-W-28560_Rev1***'.

It was confirmed during the KSAR Weekly Review Meeting on 19 January 2022 that '***RND-GRA-XX-XX-SC-W-28560_Rev1***' is the correct version. This contains The MEP Design Engineer's list of Building Services derogations and has two entries against the water and drainage services covered by SHTM 04-01. SHTM 04-01 is listed in the PEP Hierarchy of Design. NHS SA have concerns over the process for managing derogations to ensure they are appropriately and consistently recorded.

There is no evidence to suggest that the derogation list has been reviewed by the relevant stakeholders. '***RND-GRA-XX-XX-SC-W-28560_Rev1***' includes for water and drainage

services derogations. There is no evidence of a formal NHS GGC review or acceptance of the OBC design.

The detail on each SHTM 04-01 derogation is limited and there are potentially further derogations that have not been included on the list presented to NHS GGC. For example**,** the lack of filtration is listed as a derogation but there is no evidence of mitigation measures such as water quality testing or discussion with the local NHS Estates Team. The design, as described within '***RND-CDL-XX-XX-RP-ME-00214',*** proposes the use of one single piece tank located next to the boiler plant without reference on the derogation schedule. The proposed location is not in accordance with ***SHTM 04-01 – Part A***: Section 7.26, which calls for tanks to be broken down into convenient compartments.

There is no evidence that the possible adverse effect on the piped cold-water system temperature has been assessed in a ceiling void, which contains LTHW heating pipework serving ceiling mounted radiant panels.

There is no AE(W) appointed and no evidence of a Water Safety Group (WSG) review or review by any of the other stakeholders which could have a bearing on the public health designs.

Workbook Ref No.	Areas to probe	Evidence expected
2.4	Water Management Strategy	Assessment of Health Board proposed water management strategy and how this relates to the specification, guidance and project requirements. What involvement has there been from the water management group?

NHS Scotland Assure Observations:

There is no evidence that the Board has engaged with stakeholders on the water management strategy.

Presented documentation includes the MEP Design Engineer's report '***TDN 03 – Water Management Strategy****'*. This report identifies the systems which have been designed to minimise the risk of bacteria, as represented on the drawings and design report. The report aligns well with the design drawings and design report presented for review.

TDN 03 identifies how the proposed water services systems are to be monitored and managed in use and provides some evidence to support the design decisions made by the MEP Design Engineer. The report also includes some management actions understood to be partly presented as mitigation for the lack of filtration, which is a proposed project derogation.

While the lack of a centralised hot water circulation system is cited as a benefit in controlling the ceiling void cold water pipework temperature there is no evidence on how the proposed radiant panel heating system will affect ceiling void and cold-water distribution temperature.

The draft TM 52 report does not demonstrate computer modelling of the ceiling void temperatures and there is no other Dynamic Simulation and Thermal Modelling (DSM) provided for the ceiling void spaces.

It is unclear whether NHS GGC have reviewed TDN 03, which is an important document that may define the Health Board's their water management requirements and maintenance commitment to the facility going forward. There is no evidence to demonstrate that this Water Management Strategy document has been reviewed and accepted by the appropriate stakeholders or Water Management Groups. There is no evidence to suggest any involvement from the Water Safety Group (WSG) and no AE(W) has been appointed during OBC stage.

There is no evidence of how NHS GGC will manage the system presented in the design, while the facility is in use.

Workbook Ref No.	Areas to probe	Evidence expected
2.5	Water governance arrangements	Has the Health Board commenced its water governance planning and recorded how it will ensure appropriate numbers of trained staff (AP and CP) and AE(W) will be appointed, is there an established project water management group that ensures the water management strategy is adhered to for the Board, and is it clear how this project will interface with this existing group? Evidence that the Health Boards AE(W) have been involved with and reviewed the design proposals to date.

NHS Scotland Assure Observations:

There is no evidence to suggest that NHS GGC has commenced its water governance planning and no evidence of any engagement with the AE(W) or WSG. There is no plan to identify how the water management strategy, prepared by the MEP Design Engineer, will be adhered to by NHS GGC during the day-to-day running of the facility. This planning would appear to have been identified by the PSCP as an FBC stage exercise.

The PEP, Section 3.3 identifies that "*A Project Steering Group will be formed from commencement of FBC Stage. The PSG's primary purpose will be to provide technical oversight to the project and provide a link to various stakeholders, such as the NHS GGC Authorising Engineers, MHRA, etc*. "

There is no water services schematic. This is a fundamental omission from the OBC package.

There is no recorded evidence to suggest that the Water and Internal Plumbing / Drainage System designs have been reviewed by an Authorising Engineer AE(W) appointed by NHS GGC. ***The Project Execution Plan (PEP)*** identifies in Section 10.7 that the "*Authorising*

Engineer (Water) – to be confirmed as required" by NHS GGC. This is something that appears to have been postponed until FBC stage. In the opinion of NHS Scotland Assure, based on the evidence provided, including how NHS GGC have governed the process, the design ultimately includes an element of risk, which NHS GGC intend to carry forward to FBC stage. NHS Scotland Assure recommend water governance planning and engagement with the AE(W) and WSG should be addressed before FBC stage.

3.2.2 Water and Internal Plumbing / Drainage Systems: Further Observations

In addition to the points raised via the KSAR workbook above, we also include the following observations as a result of the review, all of which relate to the evidence presented during the appraisal.

3.2.2.1	There is no evidence of the incoming water quality sampling, water quality records, Soil Investigation (SI) reports or discussions on the water, gas and below ground drainage connections with the appropriate authority be it public or private. Final water connections are identified as To Be Confirmed (TBC) and the impact on other live buildings when making a new connection are not considered. The proposals do not appear to take cognisance of any other potential contaminants or SHTM 04-01 requirements, including but not limited to SHTM 04-01 Part A, 6.5. NHS GGC also note a Pre-Development Enquiry (PDE) application to Scottish Water and Scottish Environmental Protection Agency (SEPA) application are to be submitted by the PSCP team at next stage. This is considered a risk, which could have been addressed at OBC Stage and should be addressed prior to FBC stage.
3.2.2.2	There is no water services schematic, or a drainage services schematic as recommended within BSRIA BG6 for a Stage 2 design within the OBC deliverables. This is a fundamental omission from the OBC package.
3.2.2.3	SEPA was identified at the project kick off meeting as an interested party who would require to be consulted on the drainage from the facility. There is no evidence of discussion with SEPA on the drainage or how the drainage from rooms M005 and M002 are to be discharged. There is no below ground drainage information. It was suggested that an existing SEPA discharge consent / license for the site may cover the new facility, but this was not documented. This is considered a risk which could have been addressed at OBC Stage and should be addressed prior to FBC stage.
3.2.2.4	Within the design report, section 3.3.1 there is a statement that "*In order to minimise any potential bacterial growth or water stagnation within the system, dead legs will be kept to no longer than twice the supply pipe diameter*".

	There is no evidence that NHS GGC have accepted this position. There is no water risk assessment identifying how these proposed dead legs will be managed.
3.2.2.5	There is no evidence that the pipework calculation methodology has been identified and agreed with Water Safety Group.
3.2.2.6	The drawings, specifications, and schedules do not indicate any means for an emergency water supply fill point for the tanked system in the event of a failure of the single incoming mains water supply to the facility. The resilience report, '***TDN 01 - MEP Resilience Technical Note***' identifies the small water storage tank is providing resilience for the laboratory space water supply. It does not consider how the small tank would be filled in the event the loss of Mains Cold Water was prolonged. This is not in accordance with SHTM 04-01 Part A, 3.2 "*Provision should be included for alternative water supply arrangements to meet an emergency, regardless of the source or sources of supply finally adopted.*"
3.2.2.7	***SHTM 04-01 Part A*** notes that the design and installation of the cold-water distribution system should comply with the ***Scottish Water Byelaws 2004*** and relevant parts of ***BS6700: 2006, BS EN 806-2: 2005 and BS8558: 2011***. These documents are not all referenced in the document package.
3.2.2.8	There is no evidence that the height of the AHU from floor level has been selected to ensure that drainage trap depths and maintenance access can be accommodated.

3.3 Ventilation

3.3.1 Ventilation: KSAR Observations

Workbook Ref No.	Areas to probe	Evidence expected
3.1	Has the Health Board completed competency checks on the ventilation consultant designers?	Recorded evidence that the design team are experienced and have a comprehensive knowledge of the relevant design standards. Where anyone does not have a record of extensive health care experience what recorded plans are to be put in place by the Consultant Designers? Recorded evidence that input from the Health Boards Authorising Engineer for Ventilation (AE(V)) has been requested.

NHS Scotland Assure Observations:

There is no primary evidence provided within the OBC submission that directly identifies the MEP Design Engineer's experience in ventilation design. There is, however, secondary evidence which confirms that NHS GGC have reviewed and scored a Written Quality Submission, provided by the PSCP as part of the selection process. This required them to provide evidence of their proposed consultants and key individuals including Curriculum Vitae (CV) under the heading of "*Proposed Personnel".*

The Quality Submission also requested evidence of the PSCP's proposed MEP Designer's relevant similar experience, including case study examples. Whilst evidence of the process is provided, NHS SA were not provided copies of the actual CVs for review.

There is no recorded evidence to suggest that the Ventilation Systems designs have been reviewed by an Authorising Engineer AE(V) appointed by NHS GGC. The Project Manager Project Execution Plan (PEP) *'**19945 GGC Radionuclide Dispensary - PEP Rev 7 28.10.21**'* identifies in Section 3.3 that "*A Project Steering Group will be formed from commencement of FBC Stage. The PSG's primary purpose will be to provide technical oversight to the project and provide a link to various stakeholders, such as the NHS GGC Authorising Engineers*".

There is no evidence of any correspondence with or reviews from an AE(V) or the Ventilation Safety Group (VSG). It is suggested in the PEP that an AE(V) will be required to be consulted at FBC stage.

Workbook Ref No.	Areas to probe	Evidence expected
3.2	How does the Health Board ensure that ventilation services are designed in a fashion, which will retain space for minor additions and modifications to services in the future, and there is an appropriate plant access strategy?	Evidence that the design engineers have presented their co-ordination drawings (BIM model), with space for future flexibility identified, to the Board. Evidence that the design consultant has considered and agreed with the Health Board, space for future flexibility in the service installations. Evidence that the design engineers have presented each of the main service runs plus plant rooms to the Board's Estates team and / or FM team, to highlight space for future flexibility. Evidence that the Health Board has agreed a strategy (percentage) for spare capacity and a documented allowance to be incorporated into the design. Are plant rooms, IPS sections, horizontal distribution runs and risers appropriately sized for the equipment being installed and facilitate safe adequate maintenance? Evidence that a plant access strategy for the entire ventilation system has been provided to ensure safe, adequate access, including access for cleaning.

NHS Scotland Assure Observations:

There is no evidence that the designers have presented their co-ordinated BIM model to the Board. It is stated that a full BIM model will be available at FBC stage.

The OBC Stage MEP design report ***'RND-CDL-XX-XX-RP-ME-00214'*** provides a description of the ventilation systems. The design information includes only two simplified 3D views of the main upper floor plantroom on drawing ***'RND-CDL-XX-01-DL-M-50001'***. There is no evidence to demonstrate that a fully coordinated BIM model has been developed to demonstrate the key areas of coordination / "pinch-points" and future flexibility.

The position of the main laboratory AHU within the upper floor plan indicates that there is little scope to increase or alter its location, should the need arise (for example through final plant selection).

There are derogations identified within the derogations schedule ***'RND -GRA-XX-XX-SC-W-28560_Rev1'*** in relation to the AHU. These derogations are proposed specifically in order to "*reduce the dimensions of the AHU, both the width and the height, so that it can fit in the plantroom".* There is no evidence to suggest that these derogations have been formally

reviewed by NHS GGC and there is no evidence of an AE(V) or Ventilation Safety Group (VSG) review. This represents a risk, which could see the need for an increase in the physical plantroom size. NHS Scotland Assure note it is not clear why a new building could not be designed to accommodate a fully compliant AHU.

There are elements of the ventilation design that are non-compliant with ***SHTM 03-01*** which have not been included in the current derogation schedule. The following have been identified as typical examples (not exhaustive) which could become serious non-conformances if not appropriately mitigated.

- The AHU intake is currently located above carparking spaces – ***SHTM 03-01 Part A***– Section 1.42.
- The AHU is currently located against a wall – ***SHTM 03-01 Part A*** – Section 4.5.
- Combustion equipment must not be located in the same room as the AHU**,** but the boiler plant is proposed to be in the same physical space – ***SHTM 03-01 Part A*** – Section 4.8.
- Units greater than 1m wide should have access from both sides and the unit is currently over 2m wide – ***SHTM 03-01 Part A*** – Section 4.5.

Within the mechanical design drawing packages there are no ceiling void sections or detailed building sections provided to show the various building services systems in relation to co-ordination with the Structure and Architecture.

Evidence of the appropriate ceiling void coordination/spatial fit is a key OBC stage omission with respect to the ventilation services considering they are fundamental to the building's design and function.

There is no evidence to demonstrate that the need for future flexibility with the Ventilation systems or the supporting heating systems has been included as part of the project by the PSCP. The drawings do not actively indicate any reserved future plant space or distribution space provision

The following statement has been provided as part of the KSAR evidence within ***'GGC RND OBC KSAR - Future Proofing Strategy Statement'*** on the need for Future Proofing. *"GGC confirm that over the previous 5 years, service demand has remained stable and consistent. Radiopharmaceutical manufacturer is determined by requests from nuclear medicine departments which in turn are regulated by the number of gamma cameras available. It is estimated that in RND's 40 plus year history patient demand and camera numbers have remained steady. It is not anticipated significant deviation from this position."* NHSGGC, as part of their KSAR response, quote this statement as the reason for not considering future flexibility – it is however unclear as to how they have fully considered this from an MEP services perspective.

Whilst this statement acknowledges that the services will be relatively fixed, the lack of available space to accommodate alterations to the AHU is a risk because it does not allow for any changes that may arise from the stakeholder review of the design.

The access and maintenance strategy on drawing '***RND-OBE-XX-XX-DR-28002_A&M***', makes no specific reference to the main AHU ventilation system's future replacement from within the "wet" plantroom and states that the required plant removal and lifting strategy is still to be confirmed. The removal of the louvres is also cited as a potential option for plant replacement but there is no detail to support this.

The routine access and maintenance space for the main ventilation "wet" side plant is identified on drawings '***RND-CDL-XX-01-DL-M-50001***' and '***RND-CDL-XX-01-DL-M-50002***' along with a strategy for cleaning the main louvres. These Access and Maintenance drawings only consider access for personnel using mobile platforms and not the plant lifting and replacement strategy using a crane.

A crane is identified as a requirement for the mechanical plant replacement but the proposed access route and required size of crane is not identified. The strategy acknowledges there are limitations on the available site access but without any mitigation measures. This is a risk at OBC stage which should be considered before FBC stage.

General access routes through the "dry" side plantroom have not been identified to facilitate ductwork cleaning, damper maintenance and heater batteries etc. This access needs to be considered along with the identified escape routes on drawing '***RND-OBE-XX-00-DR-A-68001***'.

The laboratory ventilation systems are relatively complex in nature and the main AHU appears to be driving the main plantroom size and location. The AHU and laboratory ventilation are fundamentally at the very centre of the building's design. It is not clear from the evidence provided as to how NHS GGC have considered the requirement for spare capacity within the ventilation infrastructure.

Workbook Ref No.	Areas to probe	Evidence expected
3.3	How does the Health Board assure itself that all variations / derogations, which may be required to the ventilation systems, are investigated and agreed by all parties before they are incorporated in the design?	Evidence that the each variation / derogation has a detailed technical analysis, has been referred to the Health Board, and agreed with their ventilation safety group, clinical, engineering, Estates, infection control and FM teams.

NHS Scotland Assure Observations:

There is no evidence of derogation reviews with the board and their stakeholders.

The MEP Design Engineer's list of Building Services Derogations has five entries against the ventilation services covered by ***SHTM 03-01 Part A*** with respect to the laboratory or "hot" area ventilation system. There is no evidence to suggest that the derogation list has been formally reviewed by the relevant stakeholders.

Given the laboratory ventilation system is a fundamental element of the building's design and the evident pressure on the plantroom space then any risk associated with it that exists at OBC stage is considered significant by NHS SA.

SHTM 03-01 is listed in the PEP Hierarchy of Design along with *'EUP GMP Volume 4 Annex 1',* which is stated as being relevant to the laboratory ventilation system design and airflow regimen.

The OBC Stage MEP design report ***'RND-CDL-XX-XX-RP-ME-00214'***, identifies that the Laboratory AHU will be fully compliant with SHTM 03-01 but a number of proposed / significant derogations from ***SHTM 03-01*** are included on the derogation schedule.

There are no derogations presented against '***EUP GMP Volume 4***' or the ACRs document '***Aseptic facility specification - RND NHSGGC 16 12 19 Version 1.2***' although it has been identified during the KSAR Ventilation Workshop on 25 January 2022 that some may exist.

The detail on each ***SHTM 03-01*** derogation is limited and there are potentially further derogations identified through the KSAR that have not been included on the list presented to NHS GGC. The following have been identified which could all put increased pressure on the proposed plantroom space.

- The AHU intake is currently located above carparking spaces – ***SHTM 03-01 Part A*** – Section 1.42.
- The AHU is currently located against a wall – ***SHTM 03-01 Part A*** – Section 4.5.
- Combustion equipment must not be located in the same room as the AHU**,** but the boiler plant is proposed to be in the same physical space – ***SHTM 03-01 Part A***– Section 4.8.
- Units greater than 1m wide should have access from both sides and the unit is currently over 2m wide – ***SHTM 03-01 Part A***– Section 4.5.
- A refrigerant leak detection system should be provided in the AHU but is not referenced in the design report or identified on schematic '***RND-CDL-XX-XX-SM-M-57001***'– ***SHTM 03-01 Part A*** – 3.58.

There is no AE(V) appointed and no evidence of a review by the VSG or any of the other stakeholders referenced above.

Workbook Ref No.	Areas to probe	Evidence expected
3.4	Does the Health Board have a strategy for ventilation (for rooms where this is permitted within the SHTM/SHPN guidance)?	Evidence of agreed environmental matrix. Evidence that the Dynamic thermal modelling confirms what the design must include (e.g. structure, solar shading/protection, orientation, equipment optimisation, etc.) to ensure that room temperatures comply with SHTM guidance, in naturally ventilated rooms. Floor plans with associated plant locations highlighted plus simple schematic of strategy.

		This must also identify the air intake and exhaust strategy / locations.

NHS Scotland Assure Observations:

The Environmental Matrix has been used to inform design strategy and the space planning aspects of plant and equipment. The Environmental Matrix is included as an appendix to PSCP document '***RND-CDL-XX-XX-RP-ME-00214'.*** There is no evidence to confirm this Environmental Matrix has been reviewed and accepted by NHS GGC.

The Environmental Matrix provided uses the NHS Scotland Assure template. The Environmental Matrix document provided is dated 1 June 2021 version v1.0. The Mechanical Drawing revisions date back to 2020. The date on the Environmental Matrix was clarified during the weekly KSAR review meetings with the NHS GGC team. NHS GGC confirmed they had transposed the detail onto the new template but the technical data remained the same as that used to inform the drawings prior to 2020.

The KSAR has identified some minor errors and inconsistencies with the Environmental Matrix with respect the proposed design drawings presented. The Environmental Matrix is otherwise comprehensive and clear and largely consistent with the design information presented for review.

Only some of the office accommodation spaces i.e., the "cold" side areas out with the laboratory spaces are identified as being naturally ventilated. The majority of the laboratory and office spaces are either fully mechanically ventilated or have a mixed mode ventilation strategy.

The "DRAFT" CIBSE TM 52 calculation shows compliance with the overheating requirements but notes the following caveat *"The assessment found that all analysed spaces would pass the TM52 criteria under the analysed climate scenarios, based on the provision of a ventilation opening to achieve the equivalent areas (EA) reported in Section 3 of this report. The results indicate that in each space an equivalent area (EA) of 5-10% (of floor area) will be required to pass the TM52 criteria for both the current and 2030 scenario*."

No evidence could be found within the information presented that the window design requirements from the overheating analysis have been incorporated into the corresponding Architectural design packages. This should be addressed during the next stage of the design, in conjunction with the relevant recommendations within CIBSE applications manual AM10.

The report has not been updated from "DRAFT" for a formal issue to NHS GGC for review and acceptance.

Drawings and schematics have been provided showing the ventilation layouts, routes and plant locations. The schematic only shows the strategy for the more complex "hot" side laboratory spaces and there is no schematic available for the office or "cold" side rooms.

The design includes only two simplified 3D views of the main upper floor ventilation plantroom on drawing '***RND-CDL-XX-01-DL-M-50001'.***

There is no evidence to suggest that a fully coordinated BIM model has been developed at to demonstrate the key areas of coordination.

The air intake and discharge locations are identified on the drawings on opposite sides of the upper floor plantrooms. This ensures the required minimum separation of 4m is exceeded. A strategy for cleaning the louvres is identified on drawing '***RND-OBE-XX-XX-DR-28002_A&M***'. There is no evidence that this has been reviewed by NHS GGC Estates. It includes for access using mobile platforms in areas that may be difficult to access.

There is no evidence to demonstrate consideration of the impact of any existing and retained trees immediately behind the extract louvre to the South. The AHU intake is currently located on the upper floor but directly above a number of proposed car parking spaces in conflict with ***SHTM 03-01 Part A*** – Section 1.42.

Workbook Ref No.	Areas to probe	Evidence expected
3.5	Is there evidence of stakeholder input to ventilation strategies?	Addition to or supplement to the Environmental Matrix which confirms the following, on a room by room basis: a) The type of ventilation (to SHTM 03-01) b) Patient group and / or function related to the space. c) Name of the Consultant, Clinical Lead or Department Lead who has agreed to the room requirements. d) Name of the Infection Prevention and Control Doctor or equivalent who has agreed to the room requirements. e) Name of the Infection Prevention and Control Nurse who has agreed to the room requirements. f) Name of the Estates / FM team representative who has agreed to the room requirements. g) Name of the NHS Project Manager who has agreed to the room requirements. h) Name of the Decontamination Manager who has agreed to the room requirements (where this is part of the project).

NHS Scotland Assure Observations:

There is no evidence to suggest that the ventilation system design has been formally reviewed by the relevant stakeholders, including the laboratory users or infection control teams.

There is no AE(V) appointed and no evidence of a Ventilation Safety Group (VSG) review or review by any of the other stakeholders referenced above which could have a bearing on the mechanical systems designs.

The ventilation air change rates (ACH^{-1}) and airflow regimes are shown on the design information provided for the laboratory spaces. Ductwork sizes are also indicated on the drawings. In particular the ventilation drawings '***RND-CDL-XX-00-DL-M-57003***' and '***RND-CDL-XX-XX-SM-M-57001***' provide the detail for the laboratory ventilation strategies. The OBC report identifies that the primary laboratory AHU will be "*fully compliant with the current SHTM 03-01*". Despite the PSCP making this statement, the KSAR has identified elements of the design are non-compliant with ***SHTM 03-01*** and derogations to ***SHTM 03-01*** are also included.

The PEP states that the laboratory system is being designed to '***EU GMP Volume 4 Annex 1***'. The office space AHU has not been designed to ***SHTM 03-01*** standards although this is not specifically listed on the derogation schedule – NHS GGC have identified within the project documentation that the office space ventilation will be designed to the Scottish Technical Handbook Non Domestic – therefore no derogation would be expected in this respect.

Workbook Ref No.	Areas to probe	Evidence expected
3.6	Is there evidence of the Health Board developing Ventilation Commissioning Proposals?	Evaluation of the suitability of the proposed plans in the context of the OBC, are these sufficient do the meet the requirements of the project, guidance and the design of the system?

NHS Scotland Assure Observations:

There is no evidence to suggest that NHS GGC has started developing its ventilation commissioning proposals.

Workbook Ref No.	Areas to probe	Evidence expected
3.7	Has the Health Board started developing its ventilation governance arrangements?	Is the Heath Board considering how it will ensure appropriate numbers of trained staff (AP and CP) and AE(V) for the project? Evidence that the Health Boards AE(V) have been involved with and reviewed the design proposals to date.

NHS Scotland Assure Observations:

There is no evidence to suggest that NHS GGC has commenced its ventilation governance planning and no evidence of any engagement with the AE(V) or VSG.

NHS GGC have not as yet appointed an AE(V). There is no evidence to identify how the ventilation strategy is managed by NHS GGC. There is no evidence of a review by any of the key project stakeholders which could ultimately have a bearing on the mechanical systems designs. NHS Scotland Assure recommend formal record of the reviews should be provided at OBC stage to avoid any uncertainty or risk being carried forward to the next stage in the process.

3.3.2 Ventilation: Further Observations

In addition to the points raised via the KSAR workbook above, we also include the following observations as a result of the review, all of which relate to the evidence presented during the appraisal.

3.3.2.1	There is a conflict in the information contained in the ACRs regarding HEPA filter access. ***Guidance for Planning, Design and Construction of new and upgraded Aseptic Facilities Issue 1.2 December 2019*** - "*Access to change the HEPA filters from above is preferred and therefore plant room construction should support this"*…."*Access to change the HEPA filters from above needs to be established*". ***User Requirements Specification for Radionuclide Department Issue P06 October 2021*** "*HEPA filter housing must be a proprietary housing for standard sized HEPA filter. Housing must have room side replaceable arrangement and upstream sample point accessible within the room*" Drawing '***SM-M-57001 Issue P02'*** March 2020 shows the proposed HEPA filters in the room rather than the accessible plantroom.
3.3.2.2	There is no reference made to the key AHU / DX Cooling / Pressurisation Unit (PU) systems within the resilience strategy document '*TDN 01 - MEP Resilience Technical Note'*. These are key items of plant which are required to support the main laboratory ventilation system's continued reliable operation.
3.3.2.3	There is no evidence that the humidification requirements of the facility have been considered and assessed before excluding them and in lieu of this including space in the AHU for a retrofitted humidifier. Drawing '*RND-CDL-XX-00-DL-M-57003'* notes 35% to 75% Relative Humidity (RH) is required in the various laboratory manufacturing spaces. There is no study to identify how this could be maintained at all times without humidification Space for a future humidifier is included within the AHU. No information is included to identify that the wider water, drainage and electrical design includes for the capacity to support the installation of a humidifier, if required.

3.3.2.4	Drawing '***RND-CDL-XX-00-DL-M-57001'*** identifies that the transfer hatches will be supplied with a balanced Supply & Extract airflow served from the primary AHU. There appears to be no evidence to support the OBC stage assumption of 30 l/s for each hatch. It is not clear what this assumption is based upon, whether it has been reviewed with stakeholders and if this is a reasonable assumption or a risk. NHS GGC have noted that the final specification cannot be closed out at OBC stage because the project must allow for the selection of final plant and equipment to be on an "equal or approved basis". The stage 2 clarifications within folder 11 notes "*Until the ventilation requirements for the hatches are confirmed, technical design for the ventilation systems and the sizing of the AHU cannot be progressed*" and that this could "*have an impact on the cost of the unit and the space coordination in the plantroom*". There is no evidence that the design is based on and appropriate range of values. NHS Scotland Assure note if the assumption is incorrect then this could affect the AHU selection and size.
3.3.2.5	The design does not confirm where the LEV fans are to be located. This is listed as a CDP element within folder 07 but no specialist has been engaged at the OBC stage. Spaces should be under negative pressure and the fans located externally or as close to external as practically possible as identified within ***SHTM 03-01*** – Section 5.6. There is nothing identified on the access and maintenance strategy for the LEV fans. Only the proposed solar PV on the roof is identified on '***RND-OBE-XX-XX-DR-28001_A&M'*** which potentially could clash with the LEV fans based on the ducting routes shown on '*RND-**CDL-XX-01-DL-M-57001'***. The absence of this early space planning could have an impact on the building form.
3.3.2.6	The ventilation services shown on '***DL-M-57002 (P01 Feb 2020)'*** do not appear to be coordinated with the fire strategy plan '***DR-A-68001-P4 (Jan 2020)***'. There are fire dampers shown on the single line ducting associated with the plantroom but not on the ground floor. This is inconsistent.
3.3.2.7	No acoustic report or daylight analysis was provided as part of the NHS GGC KSAR response.
3.3.2.8	The grades of air filtration inside the AHU are identified in the design report as a G4 pre-filter and F9 final bag filter. This agrees with the information in the ACRs. The Environmental Matrix however identifies the AHU supply filter grades as F7/G4. NHS GGC should ensure consistency across project documentation.
3.3.2.9	The QC lab is shown as a grade D space on drawing '***RND-CDL-XX-00-DL-M-57003'*** but is listed as a grade C space according to the EU GMP Grades listed in the '***Aseptic facility specification - RND NHSGGC 16 12 19 Version 1.2'***.

	The grading was confirmed as Grade D during the Technical Workshop on 25 January 2022 but there is no evidence of a full and formal review by all stakeholders.
3.3.2.10	There is no confirmation that the fresh air rate provided to each mechanically ventilated space is at least 10 l/s/person in accordance with the requirements of **SHTM 03-01 Part A** section 3.7
3.3.2.11	There is no evidence that the summer cooling recommended supply-to-room air temperature differential of -7K and +10K has been adhered to with the design as requested by ***SHTM 03-01 Part A***, 3.10. While this was confirmed at the Technical Workshop on 25th January 2022, no calculations were provided as part of the KSAR response to support this statement.
3.3.2.12	***SHTM 03-01 Part A***, 2.6 notes that separate extract ventilation will be required for sanitary facilities, lavage areas, dirty utilities and in rooms where odorous, but non-toxic fumes are likely, in order to ensure air movement into the space. The extract from the "cold" side DSR space does not reflect this and is shown connected to the general extract. No evidence has been provided as to the design guidance used for the office accommodation ventilation. The PEP states the most onerous shall be used where there is a conflict.
3.3.2.13	On the Environmental Matrix, Room A006 is identified as Naturally Ventilated but is shown as Mixed Mode on drawing '***RND-CDL-XX-00-DL-M-57002'***
3.3.2.14	On the Environmental Matrix, Room A007 is identified as negatively pressurised (-ve) but it has a balanced supply and extract rate of 10 ACH making it at neutral pressure. It was agreed at the Technical Workshop on 25 January 2022 that this needs to be amended.
3.3.2.15	Access to volume control dampers on terminal devices (as shown on the schematic ventilation drawing '***RND-CDL-XX-XX-SM-M-57001'***) will be required from inside the laboratory areas within Rooms M005, M006 & DOO3 and not from the plantroom above. The level of access required into the sealed ceilings has not been reviewed and confirmed by the appropriate stakeholders. It was agreed at the Technical Workshop on 25 January 2022 that this needs to be amended and a review with stakeholders should be held.
3.3.2.16	The ***'Aseptic facility specification - RND NHSGGC 16 12 19 Version 1.2'*** notes that the laboratory space extract air should be extracted at low level via "*removable charcoal filters*" and discharged "*at a height agreed with SEPA*". The use of charcoal filters only on LEV systems is understood to be in accordance with the stakeholder requirements, following the Technical Workshop on 25 January 2022, but there has been no consultation with SEPA on the LEV proposed system discharge.

3.3.2.17	The '***Aseptic facility specification - RND NHSGGC 16 12 19 Version 1.2'*** within the ACRs notes that the pressure relief dampers are "*to be set at low level* ". The position selected should be formally reviewed and documented by the appropriate stakeholder and amended if necessary.
3.3.2.18	The Environmental Matrix identifies that the General Extract and Dirty Extract in areas with a cleanroom supply is still "TBC". The Environmental Matrix should be concluded in advance of the OBC stage design.
3.3.2.19	The ventilation schematic is inconsistent in comparison with the corresponding layout in terms of the terminal units and number / location of Volume Control Dampers (VCDs). There is also discrepancy with the primary ductwork sizes shown on '***RND-CDL-XX-01-DL-M-50002***' and '***RND-CDL-XX-01-DL-M-57001'***.
3.3.2.20	There is no AHU section showing the overall height including the height of the supporting frame to cater for access and the required condensate trap depth. There is no evidence that access will be provided to high level viewing ports without ladder access as required by ***SHTM 03-01***.
3.3.2.21	The access door to the dry side plantroom identified on '***RND-OBE-XX-00-DR-A-68001***' *i*s not shown on drawing '***RND-CDL-XX-01-DL-M-57001*'**. There may be a coordination clash with the 450mmx 350mm extract ducting and the identified escape routes. General access routes through this dry side plantroom have not been identified to facilitate ductwork cleaning, damper maintenance and heater batteries etc.
3.3.2.22	There is no reference to the comms room cooling and UPS room cooling system resilience within the either the resilience report, '***TDN 01 - MEP Resilience Technical Note'***, or the OBC stage design report. These will be key support facilities for the laboratory rooms. There is no evidence that NHS GG& C have considered and accepted this.
3.2.2.23	The position of the external condensers is different on '***RND-OBE-XX-XX-DR-28002_A&M***' and '***RND-CDL-XX-01-DL-M-50002*'**.This inconsistency needs to be rectified.
3.2.2.24	The location of the fans on the AHU as demonstrated on '***RND-CDL-XX-XX-SM-M-57001***' should be reviewed against ***SHTM 03-01 Part A***, section 4.26. Currently the plate heat exchanger (PHE) will have unbalanced pressures i.e., one side positive and one side negative. The return air filter shown on the schematic is not identified or specified in the AHU equipment list.

3.4 Electrical

3.4.1 Electrical: KSAR Observations

Workbook Ref No.	Areas to probe	Evidence expected
4.1	Has the Health Board completed competency checks on the electrical consultant designers?	Recorded evidence that the design team are experienced and have a comprehensive knowledge of the relevant design standards. Where anyone does not have a record of extensive health care experience what recorded plans are to be put in place by the Consultant Designers? Recorded evidence that input from the Health Boards Authorising Engineer for Electrical (AE(E)) has been requested.

NHS Scotland Assure Observations:

There is no primary evidence that directly identifies the MEP Design Engineer's experience in healthcare or laboratory electrical system design. There is however secondary evidence which confirms that NHS GGC reviewed and scored a Written Quality Submission provided by the PSCP as part of the selection process that led to their appointment.

The Written Quality Submission, requested by NHS GGC from the PSCP, required them to provide evidence of their proposed consultants and key individuals including Curriculum Vitae (CV) under the heading of "Proposed Personnel".

The Quality Submission also requested evidence of the PSCP's proposed MEP Designer's relevant similar experience including case study examples. Whilst evidence of the process is provided, NHS SA were not provided copies of the actual CVs for review.

There is no recorded evidence to suggest that the Electrical Systems designs have been reviewed by an Authorising Engineer AE(E) appointed by NHS GGC. ***'19945 GGC Radionuclide Dispensary - PEP Rev 7 28.10.21'*** identifies in Section 3.3 that *"A Project Steering Group will be formed from commencement of FBC Stage. The PSG's primary purpose will be to provide technical oversight to the project and provide a link to various stakeholders, such as the NHS GGC Authorising Engineers".* Within Section 10.7 of the PEP, it is noted that the *"Authorising Engineer (Electrical) – to be confirmed as required"* by NHS GGC. It is suggested in the PEP that an AE(E) will be required to be consulted at FBC stage.

Workbook Ref No.	Areas to probe	Evidence expected
4.2	How does the Health Board ensure that electrical services are being designed in a fashion which will provide ease of access for future maintenance and which will retain space for minor additions and modifications to services in the future?	Evidence that the designers have presented their co-ordination drawings (BIM model) to the Board. Evidence that the designers have presented each of the main service runs plus plant rooms to the Health Board's FM team. Evidence that the Board has agreed a strategy (percentage) for spare capacity and a documented allowance has been incorporated into the design. Are sub stations, switch rooms, distribution Board cupboards, horizontal distribution runs and risers appropriately sized for the equipment being installed and facilitate safe, adequate maintenance.

NHS Scotland Assure Observations:

There is no evidence that the designers have presented their co-ordinated BIM model to the board. It is stated that a full BIM model will be available at FBC stage. Within the OBC package presented for review there is no evidence to show that the designers have presented each of the main service runs including plantrooms to the Board's FM team.

There is no evidence that the Board has agreed a strategy for spare capacity and that a documented allowance has been incorporated into the design. There is no evidence of load analysis calculations to support the strategy around spare capacity or that this load can be accommodated within the existing site wide electrical infrastructure. Spare capacity for BMS is highlighted within section 3.8 of the MEP Design Engineer OBC Stage MEP report ***'RND-CLD-XX-XX-RP-ME-00214 Revision P01'*** in relation to Building management Systems which states *"The approved installer will allow for 25% extra capacity on the BMS outstation for any future expansion of the building plant items."*

25% LV Switchgear spare capacity is also highlighted within note 10 of drawing Main LV Schematic (Drawing number *'**RND-CLD-XX-XX-SM-E-61001'**).*

No evidence is provided as to how distribution Boards DB/ALP and DB/RNDLP are accessed and maintained.

The level 01 plant area is currently defined as a multi-service plant area and not solely defined for electrical services. No evidence has been provided to show a co-ordinated plant room that will provide safe and adequate maintenance for all services.

The level 01 Containment Layout (Drawing Number *'**RND-CDL-XX-01-DL-E-65001'***) notes incoming cables from transformer and generator rise from level 00. Drawing Level 00 Containment Layout (Drawing Number '***RND-CDL-XX-00-DL-E-65001'***) shows an external riser however this is not shown on any architectural elevation drawings. No evidence of coordination with other services has been provided. This may also clash with louvre position at level 01.

Workbook Ref No.	Areas to probe	Evidence expected
4.3	How does the Health Board assure itself that all variations / derogations, which may be required to electrical systems, are investigated and agreed by all parties before they are instigated?	Evidence that the each variation / derogation has a detailed technical analysis, has been referred to the Board, and agreed with their electrical safety group, clinical, Estates, infection prevention and control and FM teams.

NHS Scotland Assure Observations:

There is no evidence of derogation reviews with the board and their stakeholders.

'***RND-GRA-XX-XX-SC-W-28560_Rev1'*** includes the electrical services derogation, which is incomplete and does not include NHS GGC comments or an agreed acceptance date. From a review of the derogation schedule their acceptance or otherwise would not seem to be concluded and remains open.

There is no evidence of a formal NHS GGC review or acceptance of the OBC design.

Within derogation list reference '***RND-CDL-XX-XX-SC-MEP-Derogations Schedule'*** a reduction in fuel storage derogation is noted however the starting figure of 48 hours does not match with ***SHTM 06-01*** 8.84 which states "*In addition, a fuel oil main reserve for 200 hours' full-load running for each standby generator set should be available on site."* There is no evidence that NHS GGC have accepted this.

In the absence of detailed resilience assessments, NHS Scotland Assure are unable to determine currently whether there are further areas of the design that may be non-compliant with relevant guidance at this time.

Workbook Ref No.	Areas to probe	Evidence expected
4.4	Has the Health Board assured itself of availability of adequate supply from the local utility infrastructure?	Confirmation from the Regional Electricity Company as to how the supply will be provided from their network and if single or dual supplies are being made available.

NHS Scotland Assure Observations:

There is evidence presented in the form of design proposals and technical notes as to how the supply will be provided. The Radionuclide design team have summarised the alterations to the HV infrastructure within the following locations:

- TND 02 *'**Utility Technical Note'*** (Dated 18/10/2021)
- TDN 04 *'**High Voltage Infrastructure Technical Note'*** (Dated 20/10/2021)
- Drawing number *'**RND-CDL-XX-00-DR-E-65002 -rev P02'***, titled *'Radionuclide Department Electrical Connection'*

Within the TDN04 *'**High Voltage Infrastructure Technical Note'***, it describes the general high-level proposals for high voltage disconnection, alterations, and re-connection of the HV network including estimated down periods.

There is no evidence of a review of the condition of existing HV and IT infrastructure.

There is no evidence that an assessment has been carried out taking into consideration the impact of the new connection and load demand on the wider site capacity including future provision and growth.

TDN 04 *'**High Voltage Infrastructure Technical Note'*** (dated 20/10/2021), it is noted that "*Meetings will be arranged with the Gartnavel Estates, GGC and the main contractor to discuss and agree the necessary steps to accommodate the proposed shut down periods and frequency*." No further evidence is provided regarding investigations.

There is no evidence of an electrical resilience meeting to participate in an assessment of risk categories in accordance with ***SHTM 06-01***. NHS Scotland Assure would expect this document to be in place at the OBC stage to evidence a review of standby power provision, single points of failure (including on fuel systems), redundancy of plant, diverse cable routes and fire protection measures for life safety systems. The Gartnavel site wide infrastructure does not appear to have been reviewed, including cable routes and configuration of switchgear.

Workbook Ref No.	Areas to probe	Evidence expected
4.5	Evidence of provisions for emergency supplies during loss of the utility incoming supply.	Floor plans with standby generator locations highlighted plus simple schematic. Capacity of generators. UPS provision.

NHS Scotland Assure Observations:

There has been evidence provided which outlines the generator strategy, however the strategy does not include consideration of key elements including the sizing of the generator, fuel storage and maintainability. Specifically, calculations and a clear strategy to support the sizing, available fuel storage and maintainability.

Several drawings including External Lighting Layout (Drawing number *'**RND-CDL-XX-XX-DL-E-63001**'*) highlight the location of the generator compound. No further evidence has been provided detailing the location of generator, fuel point, tank etc within the compound. There is no dedicated drawing for the generator compound. It is therefore unclear how NHS GGC have validated the feasibility of the proposed location.

The generator and proposed control philosophy is noted on drawing Main LV Schematic (Drawing number *'**RND-CLD-XX-XX-SM-E-61001**'*) and within section 2.2. of The MEP Design Engineer's OBC report.

There is no evidence of a concept earthing schematic highlighting nor is there any evidence as to how an earthing system remains present in the event of loss of mains.

There is no evidence to show that start up efficiencies of the proposed generator have been considered as part of the assessment when sizing. The MEP Design Engineer's resilience report notes that the generator is sized to support 100% of the electrical supply to the building however no evidence of load calculations utilising benchmarked values together with significant loads as per section 3 of ***SHTM 06-01*** have been provided.

There is no evidence in relation to generator fuel storage calculations and associated risk assessments.

Floor plans on drawing Level 01 Containment Layout (Drawing Number ***'RND-CDL-XX-01-DL-E-65001'***) indicate allocated space for the UPS however no evidence of the UPS is shown in schematic form. There is no evidence to demonstrate that the UPS room within the first floor plant room is suitable for the equipment proposed, nor is it evident if NHS GGC have considered the environmental criteria such as room temperature or cooling that will be required to facilitate the installation.

It is noted within section 2.3 of the MEP Design Engineer's OBC Stage report that the UPS will be sized at 5kVA with an autonomy time of 10 minutes. No evidence has been provided in terms of supporting load calculations or battery autonomy calculations (including ambient operating temperatures).

No evidence is provided as to whether the UPS is single or three phase and therefore no assessment can be made in relation to the use of zig zag transformers within any 3 phase UPS as defined within ***SHTM 06-01*** clause 16.14. No evidence has been provided on the quantity of UPS's and whether these require to be in an N+1 arrangement.

Workbook Ref No.	Areas to probe	Evidence expected
4.6	Is there a strategy for locating substations?	Floor plans with substation locations highlighted plus simple schematic.

NHS Scotland Assure Observations:

There is no evidence of internal layouts of the substation, detailing trenching, equipment**,** or spatial coordination. The KSAR response does not clearly demonstrate how NHS GGC have considered the feasibility or logistics of connecting to the existing HV infrastructure, including any associated works around the Gartnavel site, specifically the connection to HV section boards and required isolations.

The LV substation is located on several drawings including External Lighting Layout (Drawing number ***'RND-CDL-XX-XX-DL-E-63001'***) and the concept strategy around HV alterations is detailed within report Connection to HV ring is defined including shutdowns

and isolations on TDN 04 *'**High Voltage Infrastructure Technical Note'*** (Dated 20/10/2021).

The transformer is detailed within the Main LV Schematic (Drawing number *'**RND-CLD-XX-XX-SM-E-61001'***) however there is no evidence of a HV schematic.

Workbook Ref No.	Areas to probe	Evidence expected
4.7	Is there a strategy for locating switch rooms?	Floor plans with switchroom locations highlighted plus simple schematic.

NHS Scotland Assure Observations:

The low voltage main switchboard is located within the level 01 plant room. This is detailed on The MEP Design Engineer's drawing Level 01 Containment Layout (Drawing Number *'**RND-CDL-XX-01-DL-E-65001'**).* The architectural plan drawing *'**RND-OBE-XX-OO-DL-A-00001-P8**'* denotes equipment layouts however as this is not shown on the MEP engineers design information. The switchgear is noted as top entry/exit.

There is no evidence highlighting that the switchgear location and setting out has been coordinated with other disciplines for example structural engineer for plinths. No information from the Structural Engineer related to this item has been provided for review.

Evidence of Switchgear form/type, specified as Form 4 type 6, is on drawing number *'**RND-CLD-XX-XX-SM-E-61001'**.*

Evidence which confirms that system harmonics have been considered is included within The MEP Design Engineer's OBC report section 2.2. The report notes that "*space within the main switchboard will be allocated for future Harmonic filter. This will be added in the future to allow the profile of the building to be generated over a twelve-month period. This will reduce the risk of the harmonic filters being oversized and provide cost effective solution*." There is no evidence that this has been discussed and agreed with relevant stakeholders. The project documentation is also unclear as to who will undertake this e.g. will it be included within the PSCP contract?

Evidence of interlocking arrangements is identified on the electrical distribution schematic Electrical - Main LV Schematic (Drawing number *'**RND-CLD-XX-XX-SM-E-61001'***). No evidence has been provided that this arrangement has been reviewed by relevant stakeholders.

Workbook Ref No.	Areas to probe	Evidence expected
4.8	Is there a strategy for locating Medical IT distribution equipment?	Floor plans with Medical IT Board locations highlighted plus simple schematic. Compliance with BS7671 section 710. Compliance with SHTM 06-01.

From the evidence provided, it is unclear how NHS GGC have assessed any requirement for Medical IT distribution equipment. There is a column within the environmental matrix that is intended to note the number of Medical IT socket outlets, which is noted throughout as stating "as per drawings".

There is no evidence on the drawings to indicate any Medical IT infrastructure, nor evidence of any assessment as to the requirement for Medical IT infrastructure in accordance with ***BS7671 Section 710*** or ***SHTM 06-01***.

Given the nature of the facility, this type of supply may not be required, however NHS GGC should ultimately ensure the assessment of such requirements is fully documented.

Workbook Ref No.	Areas to probe	Evidence expected
4.9	Is there a strategy for distribution?	Floor plans with containment distribution routing (horizontal and vertical).

NHS Scotland Assure Observations:

The electrical engineer's drawings show a strategy for electrical distribution. This is detailed within the following information:

- The MEP Design Engineer's drawing Level 00 Containment Layout (Drawing Number ***'RND-CDL-XX-00-DL-E-65001'***)
- The MEP Design Engineer's drawing Level 01 Containment Layout (Drawing Number ***'RND-CDL-XX-01-DL-E-65001'***)

Containment is allocated for sub main LV cabling, final circuits and comms in the form of cable ladder, cable tray, cable basket and trunking. This information defines horizontal and vertical routing, however, no further evidence has been provided to coordinate internal vertical routing.

The OBC documentation notes within 2.2 of the MEP Design Engineer's OBC Stage report that the transformer and generator cabling utilise the same route and trench from the external compound to the radionuclide department building. No evidence is provided that diverse routing of these cables has been considered to provide protection on primary and secondary incoming power supplies.

There is no evidence provided in relation to the physical location of electrical changeover equipment.

There is no evidence provided in relation to co-ordination and isolations required to facilitate the connection between new and existing infrastructure.

There is no evidence as to whether any assessment has been made as to whether the existing infrastructure can support the proposed works and little evidence of wider stakeholder consultation.

Workbook Ref No.	Areas to probe	Evidence expected
4.10	Is there evidence of the Health Board developing electrical commissioning proposals?	Evaluation of the suitability of the proposed plans in the context of the OBC, are these sufficient do the meet the requirements of the project, guidance and the design of the system?

NHS Scotland Assure Observations:

There is no evidence to suggest that NHS GGC has started developing its electrical commissioning proposals.

Workbook Ref No.	Areas to probe	Evidence expected
4.11	Has the Health Board starting on its early thinking for the electrical governance arrangements for the operational phase?	Is the Health Board considering how it will ensure appropriate numbers of trained staff (AP(HV), AP(LV), CP(HV), CP(LV), AE(HV) and AE(LV) for the project, inclusive of third party providers? Evidence that the Health Boards AE(E) have been involved with and reviewed the design proposals to date.

NHS Scotland Assure Observations:

There is no evidence to suggest that NHS GGC has commenced its electrical governance planning and no evidence of any engagement with the AE's (HV & LV), AP's (HV & LV) or CP's (HV & LV).

There is no recorded evidence to suggest that the Electrical Systems designs have been reviewed by an Authorising Engineer AE(E) appointed by NHS GGC. The TG Project Execution Plan (PEP) identifies in Section 10.7 that the "*Authorising Engineer (Electrical) – to be confirmed as required" by NHS GGC.* This is something that has only therefore been identified as a requirement at FBC stage.

3.4.2 Electrical: Further Observations

In addition to the points raised via the KSAR workbook above, we also include the following observations as a result of the review, all of which relate to the evidence presented during the appraisal.

3.4.2.1	Section 2.9 of the MEP Design Engineer's report '***RND-CLD-XX-XX-RP-ME-00214***' (Revision P01 dated 06/03/2020) notes nursing stations and wards however, this is not reflected in drawing information.
3.4.2.2	There is no evidence that NHS GGC have considered how ventilation systems will be supported during the period of time between loss of power and generator start up. In addition, there is no discussion as to whether the AHU's require UPS support or if the operation of vent is required at all times.
3.4.2.3	No evidence has been provided of a traffic assessment been carried out in relation to delivery, offloading of the new generator and future fuel deliveries.
3.4.2.4	Within the Electrical OBC design drawings, no power supplies, lighting, emergency lighting or IT are currently detailed within IT or UPS rooms.
3.4.2.5	It is noted within TDN 04 "***High Voltage Infrastructure Technical Note***" (Dated 20/10/2021), that the local estates team have had input into the proposed works, however, further evidence showing all relevant stakeholders input and review is not included, (e.g. Maggie's Centre & blood transfusion management). No evidence is provided to accurately detail how the continuity and reliability of power to these stakeholders will be maintained which is critical to their operation.
3.4.2.6	There is no evidence of resilience risk assessments around fire. For example, has a fire at transformer/generator compound been considered? Given their proximity there is a possibility that a fire could result in the primary and secondary power supplies being disabled. There is no evidence that the designers have referred to the SHTM Firecode series and medical adjacencies when determining the location of any bulk fuel storage as per ***SHTM 06-01*** 8.84.
3.4.2.7	There is no evidence of Emergency lighting information within environmental matrix '***RND-CLD-XX-XX-SC-ME-0001****-Environmental Matrix'* (Dated 01/06/2021, version 1.0.)
3.4.2.8	There is no evidence of an acoustic report particularly in relation to the location of the generator, including consideration of start up, running and testing scenarios.

3.4.2.9	There is no evidence provided of an electrical review of each specific sub group such as lighting, power, fire alarms and security by the user groups.
3.4.2.10	There is no evidence of a lighting risk assessment including input from Board/stakeholders for high-risk areas.
3.4.2.11	There is no evidence of fault level analysis or fault level calculations however Stage 2 report (The MEP Design Engineer's OBC report *'**RND-CLD-XX-XX-RP-ME-00214**'* Revision P01 dated 06/03/2020) outlines a strategy to manage fault levels on both the HV/LV networks and is to be developed during FBC (sections 2.1,2.2,2.2 & 2.8).
3.4.2.12	No clear evidence is provided as to how the transformer is to be maintained or replaced given the constraints of the external compound noted within the current design information as the transformer is located directly behind the generator with no clear information or detail noting access. Please refer to ***SHTM 06-01*** 3.49.
3.4.2.13	Photovoltaics are noted, including within the electrical distribution schematic - Folder 20/sub folder Electrical - Main LV Schematic (Drawing number '***RND-CLD-XX-XX-SM-E-6100****1'*). The schematic notes G59 relay protection however this should be G99 protection in accordance with technical documentation "***EREC G99***". No evidence is provided detailing how this may integrate into the existing electrical infrastructure.
3.4.2.14	There is no evidence of a co-ordinated surge-protection design.

3.5 Medical Gases – N/A to this KSAR

3.5.1 Medical Gases: KSAR Observations

NHS GGC have indicated there are no medical gases required for this facility. Therefore, NHS Scotland Assure consider this section not to be applicable.

3.6 Fire

3.6.1 Fire: KSAR Observations

Workbook Ref No.	Areas to probe	Evidence expected
6.1	Has the Health Board completed competency checks on the Fire Engineering consultant designers?	Recorded evidence that the design team are experienced and have a comprehensive knowledge of the relevant design standards. Where anyone does not have a record of extensive health care experience what recorded plans are to be put in place by the Consultant Designers? Recorded evidence that input from the Health Boards Fire Advisors has been requested.
NHS Scotland Assure Observations: Documentation provided shows evidence of competency checks being carried out on members of the design team and provides evaluation scores. These documents are redacted so it cannot be said who each check relates to. It should be noted that of the criteria noted as part of these checks, fire was not covered. PSCP letter '***GGC RND OBC KSAR – Board Competency Checks Statement***' notes the competency of design team members, which includes The Architect. Given the fire strategy information provided has been produced by The Architect, there is no specific evidence that competency checks have been carried out with respect to the fire strategy works carried out. While there is evidence to show input from GGC Fire Advisors, no evidence is available suggesting input in relation to competencies. A fire engineer has not been appointed to date on the project.		

Workbook Ref No.	Areas to probe	Evidence expected
6.2	Has a written fire strategy been completed and does it provide evidence, where there is a variance from statutory and mandatory guidance, that an equivalent level of safety has been	Is there documented evidence that fire suppression systems have been considered for life safety and property protection? Is progressive horizontal evacuation available for all patient areas that continuously moves away from the fire area?

	achieved by alternative means?	Does the design considerations of the fire and detection system, for in-patient facilities, provide L1 coverage including voids? Does the design provide for a compliant emergency lighting system? Are free swing arm self-closers fitted to all leafs of doors serving sleeping accommodation? Have escape lifts been considered for the evacuation of patients and others with mobility issues? Are multi sensor fire detectors installed to reduce the occurrence of unwanted fire alarm signals? Are there adequate storage facilities to ensure escape routes are not used for this purpose? Are measures in place to provide safe charging of electrical and personal electronic equipment? Have fire hazard rooms been designated based on fire load? Where there is a mechanical ventilation system - have all compartments, sub-compartments and corridors serving sleeping accommodation been designed to be fitted with fire and smoke dampers?

NHS Scotland Assure Observations:

A fire engineer has not been appointed to date on the project.A fire engineer has not yet been appointed to the project at this stage. Therefore, a fire strategy report has not been provided as part of the information received.

A single page document has been provided, which appears to be an extract from the OBC report, including basic information relating to the classification of the building and noting that fire doors have been included. However, no evidence or written explanation has been provided to advise on the intended approach to the following (with reference to the ***Non-Domestic Technical Handbook: Section 2 – Fire*** (NDTH):

- Compartmentation.
- Structural fire protection.
- Cavities.
- Internal linings.
- Spread to neighbouring buildings.

- Spread on external walls.
- Spread from neighbouring buildings.
- Means of escape.
- Escape lighting.
- Communication (fire detection and alarm).
- Fire & Rescue service access and facilities.
- Fire Suppression.

No evidence has been provided to confirm that suppression has been appropriately considered and discounted.

No information has been provided to confirm the proposed evacuation strategy for the building. As a non-patient facility, the building is not proposed to follow SHTM or Annex 2B of the NDTH.

Indicative fire alarm layout drawings ('***RND-CDL-XX-00-DL-E-67001***' and ***'RND-CDL-XX-01-DL-E-67001***') specify a category L1 fire detection and alarm system to be provided in accordance with ***BS 5839-1:2017***. Documentation provided discusses smoke, heat and combined heat and optical sensors. There is also a air sampling system included within electrical drawings. However, other than the air sampling system, it is not clear from the information provided what type of sensor is to be provided as part of a smoke detection and fire alarm system.

Current drawings suggest some corridors are shown as rooms such as ***"Support Room M004"***. It should be advised by The Architect what the proposed use of each space is with regards to adequate storage whilst ensuring escape routes remain clear.

No information has been provided to confirm the proposed approach to the safe charging of electrical and personal electrical equipment.

No evidence is available showing the inclusion of fire dampers within ventilation systems, where the ventilation is proposed to cross lines of fire compartmentation.

Workbook Ref No.	Areas to probe	Evidence expected
6.3	How does the Health Board assure itself that all variations / derogations, which may be required to fire systems, are investigated and agreed by all parties before they are instigated?	Evidence that the each variation / derogation and any fire engineering proposals are being referred to the Board and agreed with their fire safety group, clinical, engineering, infection prevention and control and FM teams.

NHS Scotland Assure Observations:

While evidence is available showing consultation has been carried out with the Health Board, no evidence has been provided to confirm that variations / derogations have been referred to the board and agreed with the relevant parties.

A small number of derogations are noted within documents *'**RND-OBE-XX-XX-SC-A-28510_Extract Derogations**'* and '***Clarifications Extract re Fire Strategy'***. These pre-date the most recent revision of fire strategy plans and as such, it is not clear if these are still current.

Workbook Ref No.	Areas to probe	Evidence expected
6.4	How does the Health Board assure itself that all fire dampers and fire/smoke dampers are designed to allow for inspection, resetting and maintenance?	Evidence that the designers have presented their co-ordination drawings (BIM model) to the Board. Evidence that the designers have presented each of the fire dampers and smoke / fire dampers to the Board's FM team. Safe and adequate access has been allocated on both sides of all fire dampers for maintenance.
NHS Scotland Assure Observations: There is no evidence provided relating to fire dampers installation of maintenance requirements and in the absence of a developed BIM model it is unclear how these have been considered currently by the designers or NHS GGC team.		

Workbook Ref No.	Areas to probe	Evidence expected
6.5	How does the Health Board assure itself that any fire rated ductwork is correctly installed?	Evidence that the system is certificated and that the installation follows the installation details which were used for the certification. Written confirmation from the design consultant.
NHS Scotland Assure Observations: The current design does not appear to include fire rated ductwork.		

Workbook Ref No.	Areas to probe	Evidence expected
6.6	How does the Health Board assure itself that any smoke control and/or clearance systems are fit for purpose?	Evidence that the smoke system is being designed by an accredited Fire Engineer. Evidence that Building Control are being consulted. Confirmation from the Building Services Design Consultant that the operating

		sequence for the smoke system has been discussed regarding being integrated into the control of other building systems.
NHS Scotland Assure Observations: The design information received does not include any form of smoke control or smoke clearance. No evidence of consultation with Building Control on the subject of smoke control or smoke clearance is provided.		

Workbook Ref No.	Areas to probe	Evidence expected
6.7	Evidence that the Health Board is ensuring fire safety input into the design process together with early design decision-making.	Input from Fire lead(s) and HFS / SFRS on fire safety into site / option selection. Documents e.g. option appraisal report, fire strategy report, meeting minutes. Demonstrable and appropriate engagement and expertise of relevant Fire lead(s). Signed off documents, e.g. reports, role profiles, minutes. Evidence that the Health Boards Fire Advisor have been involved with and reviewed the design proposals to date.
NHS Scotland Assure Observations: Evidence indicates that discussions have taken place with the health board and HFS. However, no evidence / meeting minutes has been provided to confirm input from HFS and SFRS was obtained in relation to fire safety provisions of the site and options selection. A fire strategy report has not been provided, therefore sign off has not been obtained.		

Workbook Ref No.	Areas to probe	Evidence expected
6.8	Has the Health Board started the development of the fire system outline commissioning proposals?	Has the Health Board designed appropriate trained staff and appointed a fire officer for the project, is there an established firer management group that will ensure the fire management strategy is adhered to?
NHS Scotland Assure Observations: No evidence was submitted as part of the KSAR response with regards to management policies. Therefore, no evidence is available to confirm if appropriate trained staff have been		

assigned by the health board. There is also no evidence that a fire management group has been established to ensure the fire management strategy is adhered to. While fire officers have been involved with the design process, it's not clear within the information provided if a specific NHS fire officer has been appointed to the project.

3.6.2 Fire: Further Observations

In addition to the points raised via the KSAR workbook above, we also include the following observations as a result of the review, all of which relate to the evidence presented during the appraisal.

3.6.2.1	The health board should confirm they are satisfied with the use of the Non-Domestic Technical Handbook as acceptable for the proposed building. The KSAR has identified that within the design team some disciplines are utilising guidance within SHTM documents. Given the use and type of building, it is expected that the NDTH is applicable.
3.6.2.2	It is noted that the location of a generator and transformer is yet to be specified on the proposed site. It is relevant at this stage in the design process to confirm external fire spread and compartmentation with respect to the generator and transformers has been appropriately considered.
3.6.2.3	External escape routes are shown along external elevations of the building. It is unclear whether NHS GGC have considered any requirement for fire protection to elevations in this respect.
3.6.2.4	Bin storage is shown at the base of the single stair which provides egress from the upper level plant area.
3.6.2.5	Document '***OBC NDAP Recommendations Responses v1.1'*** notes several essential recommendations within. The proposed facility is highlighted as critical infrastructure and as such should have a level of safety and resilience. Consequently, where derogations are to be found within the design, justification should be reviewed constantly and detailed through each design stage. As identified, numerous derogations are noted within the currently proposed design with no justification detailed. An increased level of resilience is not believed to be shown within the documentation provided or within the current design.
3.6.2.6	Drawing '***00-DL-ME_99001'*** identifies that the proposed new Fire Hydrant (FH) is still TBC by the Scottish Fire and Rescue Service (SFRS). There is no evidence that this approach and the proposed FH location been discussed with the NHS GGC Fire Officer. The FH proposed location appears to be on the high side of the retaining wall which may create access difficulties. FH capacity is noted as a closed out medium risk on the risk register.

	There is no evidence of the mitigation to close out this risk. At the KSAR review workshop on 25 January 2022, there was uncertainty within the project design team as to whether a new FH is required.
3.6.2.7	It is unclear from the KSAR evidence provided as to the extent that NHS GGC have considered the fire protection of the building and potential impact on business continuity in the event of a fire. This may impact on a number of risk assessments associated with the development of MEP strategies and should be fully considered by NHS GGC moving forward.

3.7 Infection Prevention & Control Built Environment

3.7.1 Infection Prevention & Control Built Environment: KSAR Observations

Workbook Ref No.	Areas to probe	Evidence expected
7.1	How does the Health Board demonstrate that there is an effective infection prevention and control management structure in place? How does the Board demonstrate leadership and commitment to infection prevention and control to ensure a culture of continuous quality improvement throughout the organisation and that there is an effective IPC structure in place; inputting into the design process?	The Health Board provides evidence that there is an IPC Management Structure with the necessary expertise and leadership skills to support the design work. The Health Board provides evidence that there is an IPC Management Team with the necessary expertise and leadership skills to support the project. Executive Board reports or minutes. Risk registers or equivalent, Minutes from operational and governance groups, (and action points). Structure of infection prevention and control team (IPCT) and qualifications held, previous experience supporting new build projects. Evidence IPC and clinical teams have been involved with any derogation through the design process and are satisfied this will not impact on patient safety. This can be meeting minutes, risk assessments, and risk registers. There is IPC evidence of escalation through the agreed NHS Board governance process. Evidence the Executive Board member assigned to lead on IPCT has been kept informed of IPC risks identified and associated with the project this can be demonstrated by the Board. Evidence that fixtures fitting and equipment

		have not been proposed for the project that would represent an IPC risk.

NHS Scotland Assure Observations:

No evidence was provided by the health board as part of the KSAR response in respect of the IPC Management Structure or IPC Management Team documenting the necessary expertise and leadership skills to support the design work. The health Board competency checks statements only refer to contracted teams. No evidence of the competency of the health board project team inclusive of pharmacists and IPCT has been provided, nor is any risk identified considering if resource is not available or experience is limited what mitigations may be required.

The derogation schedule provides no evidence that the IPC team has been involved in project derogation discussions/sign off, or that derogations have been escalated through the project governance or IPC escalation processes. The PEP details how the project will be managed and governed and that each responsible person can escalate issues, however, no evidence was provided detailing escalation processes to follow. This is inclusive of the IPC team and escalation to HAI executive lead.

The RACI matrix and PEP have identified the requirement for equippers for the project but at the time of last review and sign off, the position for this project had yet to be appointed. The documents also acknowledge the role of IPC in supporting the equipping process but as yet has not commenced.

Workbook Ref No.	Areas to probe	Evidence expected
7.2	How does the Health Board demonstrate implementation of evidence based infection prevention and control measures during the design process?	The health board evidences that: The health board can demonstrate the current version of the National Infection Prevention and Control Manual has been adopted by the organisation and all staff are aware of how and where to access this and it is being referred to during the design process. IPC work programme and planned IPC audit programme for new building taking cognisance of any actual or perceived risks identified.

NHS Scotland Assure Observations:

IPC input to project has been referenced in the RACI matrix and PEP documents however there is limited evidence to support their active involvement in the project and no evidence to demonstrate the National Infection Prevention Control Manual is incorporated into the design process. There is no reference to microbiologist or ICD support to the project. NHS GGC should consider the inclusion of this resource moving forward to FBC.

Whilst the facility is not an inpatient facility, it will manufacture radionucleotide treatments for vulnerable patient groups across the West of Scotland. The manufacture of those products is subject to MHRA regulations, however, IPC considerations will be required for staff and visitors who will work in and visit the facility. NHS GGC have not confirmed if there will be an expectation for the facility to be audited by the IPC team.

Workbook Ref No.	Areas to probe	Evidence expected
7.3	How does the Health Board assure itself that the designers have a proper understanding of the infection prevention and control procedures required?	The health board evidences that: All relevant staff within the designers' organisation are provided with clear guidance on roles and responsibilities in relation to infection prevention and control. The contractors' organisation will provide evidence of education in relation to infection prevention in the built environment for all staff involved in the project.

NHS Scotland Assure Observations:

The RACI Matrix does provide information of the role of IPC within the project, however the document contains omissions of IPC input at some critical future stages, which NHSGGC should review for moving to FBC, for example, HAI risk assessments, CDM information, construction and commissioning.

No evidence was available to ascertain the appointed contractors**'** education/expertise specifically in relation to IPC in the built environment. Whilst evidence was provided of competency checks and evaluation scores from bidding process, these do not appear to specifically address competency in respect to IPC matters.

Workbook Ref No.	Areas to probe	Evidence expected
7.4	How does the Health Board assure itself that equipment being proposed meets the required IPC standards?	The IPC Team are involved and IPC advice followed in all procurement decisions for new equipment prior to purchase. IPCT are satisfied that all equipment purchased can be decontaminated safely in line with National Guidance NIPCM and manufacturers' instructions.

NHS Scotland Assure Observations:

The facility is not an inpatient facility, but IPC input will still be required to reduce risk for staff and visitors to the facility. The PEP document notes equipping lead is to be confirmed and RACI matrix notes equipper input at FBC stage.

3.7.2 Infection Prevention & Control Built Environment: Further Observations

In addition to the points raised via the KSAR workbook above, we also include the following observations as a result of the review, all of which relate to the evidence presented during the appraisal.

3.7.2.1	No evidence is included within the HAI-SCRIBE documentation regarding job titles of all members of the project team, therefore, NHS Assure cannot ascertain if IPC and clinicians are included in the review team. There is also no evidence provided of client stakeholder review including input/sign off from clinical team and infection control team in the document or input from ICD or microbiologist as required by ***SHFN 30: Part A*** (1.2 – 1.8).
3.7.2.2	The original HAI-SCRIBE was completed in January 2021. No evidence was provided to confirm if the project team remains the same or if original members have been replaced. NHSGGC have not provided any evidence to support their approval of the original HAI-SCRIBE assessment.
3.7.2.3	Stage 2 of the HAI-SCRIBE risk assessment has not yet commenced as required by ***SHFN 30: Part A*** (4.2-4.4).
3.7.2.4	No evidence provided by NHSGGC regarding the proposed mitigations for dust or other IPC risks to other facilities/public areas within the Gartnavel site during the construction phase. The site accommodates critical clinical facilities, including cancer care/support facilities, therefore this risk must be fully considered.
3.7.2.5	***Responsibility Assignment Matrix*** – The document notes IPC input from the Lead nurse. There is no evidence of microbiologist/ICD support for the programme.

4. Appendices

Appendix 1: Glossary

Please refer to NHS Scotland Assure – Assurance Service Master Glossary document available to download from NHS National Services Scotland website

[redacted]